Ontario

Advisory Council on Occupational Health and Occupational Safety

Fifth Annual Report
April 1, 1982
to March 31, 1983

Volume 1

Mandate and Objectives

The function of the Advisory Council is and it has power to*:

a) make recommendations to the Minister of Labour relating to programs of the ministry in occupational health and occupational safety; and
b) advise the minister on matters relating to occupational health and occupational safety which may be brought to its attention or be referred to it.

To achieve this Council has set the following objectives:

Primary Objective
To advise the Minister of Labour on all matters relative to occupational health and safety in Ontario.

Secondary Objectives

1. To ensure as far as possible that the policies and programs in occupational health and safety effectively minimize the risks to health and safety in all workplaces in Ontario.
2. To ensure as far as possible that knowledge about occupational health and safety is available to management, labour and the public and that it is understood by them.
3. To assist in promoting and establishing mechanisms involving management and labour to solve problems in occupational health and safety.
4. To ensure as far as possible that there is appropriate manpower training and development for the occupational health and safety field.
5. To review periodically the effectiveness of the policies and programs implemented to achieve objectives 1 to 4. **

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*The Occupational Health and Safety Act.s 10(7).
**added June, 1980.

Advisory Council on Occupational Health and Occupational Safety

Fifth Annual Report
April 1, 1982
to March 31, 1983

Volume 1

**400 University Ave.,
15th Floor,
Toronto, Ontario
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Copies of this report are available from:

Ontario Government Bookstore
880 Bay Street
Toronto, Ontario M7A 1N8

ISSN 0708-5117

Table of Contents

Letter of Transmittal 1

Members and officers of the Advisory Council on Occupational Health and Occupational Safety 1982-83. 2

Preface 3

Introduction 6

Council's Advisory Memoranda and Minister's responses

82-I –Council's letter of April 20, 1982 forwarding report: 20
A Review by the Advisory Council of the Process Used to Develop a Standard for Vinyl Chloride and Council's Evaluation of the Criteria Utilized to Assess the Hazard of Vinyl Chloride Exposure in the Workplace. 21

–Appendix 1
Agenda for Discussion 33

–Appendix 2
Minister's letter of February 12, 1982 forwarding revised draft vinyl chloride regulation for council's review. 37

–Minister's letter of July 20, 1982 in response to Advisory Memo 82-I 39
–Ministry of Labour comments of July 20, 1982 on Advisory Memo 82-I. 40

82-II –Council's letter of June 21, 1982 forwarding report: 46
A Review by the Advisory Council of the Process Used to Develop a Standard for Coke Oven Emissions and Council's Evaluation of the Criteria Utilized to Assess the Hazard of Exposure to Coke Oven Emissions in the Workplace. 47

–Appendix
Agenda for Discussion. 56

–Minister's letter of July 20, 1982 in response to Advisory Memo 82-II. 59
–Ministry of Labour comments of July 20, 1982 on Advisory Memo 82-II. 60

82-III –Council's letter of July 12, 1982 forwarding report: 64
A Review by the Advisory Council of the Process Used to Develop an Interim Standard for Asbestos and Council's Evaluation of the Criteria Utilized to Assess the Hazard of Asbestos Exposure in the Workplace. 65

–Appendix 1
Minister's letter of March 30, 1982 forwarding draft asbestos regulation for council's review. 83

–Appendix 2
Agenda for Discussion. 86

–Minister's letter of January 4, 1983 in response to Advisory Memo 82-III. 89
–Minstry of Labour comments of December 29, 1982 on Advisory Memo 82-III. 90
–Minister's letter of February 22, 1983 concerning crystalline talc and the asbestos regulation. 93
–Council's response of March 18, 1983. 95
–Minister's letter of March 25, 1983 elaborating on points made in letter of February 22, 1983. 96

82-IV –Council's letter of January 21, 1983 forwarding report: 100
A Review by the Advisory Council of the Process Used to Develop a Standard for Noise and Council's Evaluation of the Criteria Utilized to Assess the Hazard of Noise Exposure in the Workplace. 101

–Appendix 1
Minister's letter of November 12, 1982 forwarding draft noise regulation for council's review. 119

–Appendix 2
Agenda for Discussion. 121

–Appendix 3
Deputy Minister's letter of December 30, 1982 requesting a further meeting between ministry officials and members of the task force. 126

–Minister's letter of March 8, 1983 in response to Advisory Memo 82-IV. 127
–Terms of Reference of the Special Advisory Committee on the Noise Regulation. 129
–Council's letter of March 11, 1983 commenting on point made in Minister's letter of March 8, 1983. 131

82-V –Council's letter of February 14, 1983 forwarding report: 134
Principles and Procedures for the Interpretation of Epidemiological Studies. 135
–Minister's letter of March 16, 1983 acknowledging receipt of Advisory Memo 82-V. 146
–Council's letter of April 8, 1983 forwarding Appendix to Advisory Memo 82-V. 147
–Appendix to Advisory Memo 82-V. 148
–Minister's letter of May 10, 1983 acknowledging receipt of Appendix to Advisory Memo 82-V. 191

82-VI –Council's letter of February 25, 1983 forwarding report: 194
Interim Recommendations on the Electromagnetic Spectrum and the Potential Reproductive Hazards of Visual Display Units. 195
–Minister's letter of March 9, 1983 requesting clarification of certain recommendations contained in Advisory Memo 82-VI. 203
–Council's letter of May 10, 1983 in response to Minister's letter of March 9, 1983. 206
–Minister's letter of May 12, 1983 requesting further clarification re: Advisory Memo 82-VI. 208

82-VII –Council's letter of March 17, 1983 forwarding report: 212
Concerning the Legal Interpretation of the Occupational Health and Safety Act. 213
–Minister's letter of May 4, 1983 in response to Advisory Memo 82-VII. 217

Administration 220-222

Legal mandate of the Advisory Council
Primary Objectives
Secondary Objectives
Terms of reference
Meetings

Task Forces of the Advisory Council 224-230

Terms of reference
Membership
Meetings held

Appendices

A –Injuries, Permanent Disabilities and Fatalities Receiving First Payment of Compensation in 1981 by Year-End 1982, Classified by Nature of Injury. 232

B –Fatality Frequency Rates per Million Man-hours and Numbers of Fatalities for Major Industries in Ontario, 1978, 1979, 1980 and 1981. 233

C –Compensated Work Injury Frequency Rate Per Million Man-hours for Major Industries in Ontario, 1971-1981. 234

C-1 –Number of Compensated Work Injuries for Major Industries in Ontario 1971-1981. 234

D –Injuries Receiving Compensation in 1981 by Occupation Ranked in Descending Frequency per 100 Employees Covered by the Workmen's Compensation Board of Ontario. 235

D-1 –Selected Occupations Defined by Subgroup from the Canadian Classification and Dictionary of Occupations. 236

Ontario
Advisory Council on
Occupational Health &
Occupational Safety

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Ref: File AC/A/14

April 29, 1983

The Honourable R.H. Ramsay
Minister of Labour
400 University Avenue
14th Floor
TORONTO, Ontario
M7A 1T7

Sir:

I have the honour to submit the Fifth Annual Report of the Advisory Council on Occupational Health and Occupational Safety for the fiscal year 1982-83.

I have the honour to be, Sir,

Your obedient servant

J.F. Mustard
Chairman.

Attachment

Advisory Council on Occupational Health and Occupational Safety Members and Officers 1982-83

W.A. Barnes (1983)
General Motors of Canada
St. Catharines

R.T. Boldt* (1985)
Dow Chemical Canada, Inc.
Sarnia

N. Caldbick (1983)
Housewife
Timmins

J.W. Charters (1983)
Steel Company of Canada
Hamilton

D. Dewees** (1984)
University of Toronto
Toronto

J. Duffy (1985)
Provincial Bldg. & Const. Trades Council
Don Mills

P.A. Fisher (1983)
Fisher Farms
Burlington

R.D. Fraser (1982)
Queen's University
Kingston

J. Gill (1985)
United Automobile Workers
Willowdale

L. Heard (1983)
United Steelworkers of America
Toronto

E. Kaegi** (1984)
C-I-L
Willowdale

M.D.S. Kellow (1983)
Abitibi-Price Inc.
Toronto

E. Mastromatteo (1982)
INCO Ltd.
Toronto

D.R. McCalla** (1985)
McMaster University
Hamilton

J.M. More (1983)
Energy and Chemical Workers' Union
Oakville

J.F. Mustard (1983)
(Chairman)
McMaster University
Hamilton

C.G. Pilkey (1983)
Ontario Federation of Labour
Don Mills

G.J. Samson (1982)
Safety Consultant
Toronto

G.J. Stopps (1983)
University of Toronto
Toronto

M.A. Taschereau (1983)
Dome Mines
Toronto

C.J. Tuohy** (1985)
University of Toronto
Toronto

E.A. Waddell (1983)
Ontario Federation of Labour
Don Mills

R. Wilson (1982)
Ontario Hydro
Toronto

A.D. Wolfson (1982)
Vice Chairman
University of Toronto
Toronto

V. Biggar
Research Officer

A.J. Byrne
Executive Secretary

I.S. Glasberg
Research Officer

E. Harney
Executive Assistant

G. Perry
Research Officer

N.R. Subramanian
Committee Officer

Members' terms expire on October 31 of the year indicated in parentheses.

* Appointed June 1982
**Appointed November 1, 1982

Preface

In January of this year, council, once again, had an opportunity to meet with and hear the opinions of representatives of management and labour, this time with regard to a specific issue – the control of workplace carcinogens. Although the discussion and comments were directed towards a rather narrow topic, many peripheral issues of critical concern to the whole area of occupational health and safety were brought to the fore.

The debate at this open meeting centred upon council's Discussion Paper on the Control of Workplace Carcinogens, distributed in June 1982. Readers may refer to the Discussion Paper in Volume 2 of this report. Following the Discussion Paper are the briefs submitted by companies and organizations in response to the points raised. Council hopes that the reader will take the time to review these issues and comments and to carefully weigh the various policy options available. Council members will be asked to do the same under the guidance of an expanded Special Advisory Committee. Council expects to present its advice to the minister later in 1983.

Council greatly values such opportunities for direct contact, as a group, with the parties who are involved in the application of occupational health and safety principles at the operating level.

Council has been pleased to continue its review of the procedures involved in the development of the designated substance regulations. Once again, council wishes to commend the ministry on the degree of openness that has been maintained in the process of discussing draft regulations.

Council hopes that the advice that it offered to the minister earlier this year in the form of Advisory Memorandum 82-V on the Interpretation of Epidemiological Studies will help ministry staff to streamline internal procedures involved in evaluating the scientific evidence prior to the establishment of a standard. Council's task force is continuing its deliberations on the evaluation of animal studies and the role of economic analysis in the standard setting process.

In Advisory Memorandum 82-VI, council submitted recommendations to the minister on the difficult and sensitive issue of the possible health hazards associated with the use of visual display units. These recommendations comprise the interim advice with regard to both the electromagnetic spectrum and the possible reproductive hazards. Council's advice on ergonomic matters will be submitted early in the coming year.

The Task Force on the Implementation of the *Occupational Health and Safety Act* submitted an interim report to council on the subject of legal interpretations of the Act. This formed the basis of council's advice to the minister contained in Advisory Memorandum 82-VII. The task force will continue its work this year and has assumed responsibility for a survey of joint health and safety committees throughout the province. It hopes to be able to assess the effectiveness, to date, of these committees in terms of the implementation of the provisions of the Act, the degree of understanding of the difficulties that exist in the area of occupational health and safety and the various measures that might be employed in arriving at solutions. The task force will also prepare a report to council on the role of government, and will review the application and implementation of the designated substance regulations.

Council expects to offer advice to the minister in the following areas also:

- Literacy and occupational health and safety.
- Women and occupational health and safety.
- The role of health surveillance and health screening in occupational health programs.
- The introduction of advanced technology into the workplace.

Council's objectives and terms of reference are set out in the last section of this report. Also included are the dates of council meetings and the terms of reference, membership and meeting dates of its task forces.

Council wishes to thank Mr. Peter Lewycky of the ministry's Research Branch for once again providing statistics on occupational fatalities, major disabilities, injuries and illnesses in Ontario. This information is to be found in the appendices at the end of the report.

As in past years, council acknowledges, with gratitude, the continuing support and co-operation that it has received from members of management, labour and private and public associations and agencies. The invaluable assistance provided by the non-council members of the task forces is vital to the success of council's endeavours.

A number of changes have occurred in the membership of council during the past year. Council was sorry to lose four of its original members on the expiry of their terms of office. The many years of commitment and wise counsel offered by Dr. Rod Fraser, Dr. Ernie Mastromatteo, Mr. Gil Samson and Mr. Bob Wilson are most gratefully acknowledged.

Sincere thanks also go to Dr. Alan Wolfson, who served as vice-chairman until his departure from council to take on the responsibilities of chairman of the Ontario Manpower Commission. The valuable contributions that he made during his brief tenure were appreciated by all.

Five new members joined council in 1982. Council is pleased to announce the appointments of Mr. Bob Boldt, Dr. Don Dewees, Dr. Elizabeth Kaegi, Dr. Dennis McCalla and Dr. Carolyn Tuohy.

INTRODUCTION

Technological Development: Its Impact upon Occupational Health and Safety

In past annual reports, council has considered the importance of the environment and living conditions as major determinants of human health. In last year's Introduction, it began to consider the potential impact that new knowledge and advanced technology could have on the control of health and safety hazards in the workplace.[1] Council anticipated at that time that, with proper incentives, this new knowledge and technology will be increasingly applied as a means of reducing hazards to workers and of improving the quality of working life, and that, by the end of this century, we will have the capability to ensure that the workplace environment has few, if any, negative effects on human health. In the Introduction to the fifth annual report, council will explore this subject in greater depth, and will then go on to consider a closely related topic. It believes that the time has come to consider not only what changes may be occurring in the physical environment, but also the question of the role of government in these developments and the mechanisms whereby it may provide whatever assistance is thought to be appropriate.

It is clear that the above are not topics that can be given adequate consideration in an introduction such as this. All council will attempt to do is point to some areas that may require our attention in the very near future and, in so doing, open the debate on some critical issues. It should be emphasized that in the section of this Introduction headed 'The Role of Government', council is merely suggesting that the time may be ripe for conducting a review of our institutional and administrative structures. The conclusion reached from such a thorough review may well be that there is enough flexibility built in to our present institutional and administrative framework to permit its continued use for years to come in dealing with the rapidly changing technological environment.

The discussion that follows in no way implies that council itself has reached any conclusions on the issues. There is, however, a general consensus among members on the following basic premises:

1. The health and safety implications of the introduction of new technology cannot be ignored.
2. Current adversarial relationships may not always be conducive to a speedy resolution of the problems that will inevitably arise.
3. Administrative arrangements must be such that equality of resources will be assured to the various parties who will be affected by technological change and who must be in a position to offer informed and responsible opinions on the most appropriate policies to adopt in these areas.

A Changing Environment

Changes in lifestyle and work environment, which may result from technological development, will pose increasingly complex policy and administrative problems for those whose responsibility it is to give direction and guidance in the field of occupational health and safety. In anticipating the need for greater co-ordination and co-operation between all those institutions concerned with prevention, education, exchange of data, research and planning in the area of occupational health and safety, council has asked itself some basic questions: What kind of workplace, what kind of work force and what kind of working environment are we planning for? Until such time as society reaches a consensus on these issues, we will be unable to assess the adequacy of our administrative arrangements, and will run the risk of proposing changes that are appropriate to conditions of work that may no longer exist.

What, in fact, is the nature of the changing environment that our institutions must be prepared to accommodate? The first computer control systems went on-line in industrial plants over 20 years ago. Since then, there have been rapid advances in our ability to process, compute and transmit information electronically. During the past 10 to 20 years, the trend in mass production industry has been toward more and more sophisticated engineering methods and computer-controlled advanced technology.

The Canadian government is actively promoting and encouraging the development of the electronics and micro-processing industries. Currently, Canada is estimated to have between 200 and 300 first generation industrial robots in use. However, the pressing issue is seen to be when and how Canadian industry will catch up with increasingly productive foreign competitors. It is estimated that there are about 15,000 robots in operation in Japan, 6,500 in the United States and at least 10,000 in Western Europe. Industrial robots are now employed, for example, in operating forging presses, loading and unloading machine tools, and in spray painting and welding. The first developments have been made in remote control mining equipment. Falconbridge Nickel Mines in Sudbury, for example, has developed a remote controlled scoop tram for use in areas where ground conditions are unsafe.

In the U.S., a machine known as the Thin-Seam Miner can recover up to 85 per cent of the coal within its reach.[2] The cutting head tracks the coal seam with the aid of sensors that distinguish the differing levels of natural radioactivity in the coal and in the surrounding layers of shale. It is designed to mine hillside coal seams from 24 to 63 inches high.

The use of digital computers in mining have made it possible, for example, for a dragline simulator to be programmed to teach a new operator the 'feel' of the device before he operates the actual machine.

It is expected that future gains in productivity can be made with the aid of computers to improve the co-ordination of mining systems.

New forms of technology for processing information have been adopted widely in commerce. In the office, the nature and organization of work have changed dramatically with the introduction of electronic devices for processing, storing and communicating information.

In the manufacturing area, technological development is sometimes thought of as synonymous with the use of robots designed to replace production workers. However, as was pointed out in a recent series of articles in

Scientific American on the Mechanization of Work, the direct work of making or assembling a product is not where mechanization is now likely to have the greatest impact.[3] The influence of the new data-processing technology is most significant in the opportunities provided for increased productivity through the linking of design, management and manufacturing data. The capacity of computer-controlled systems to co-ordinate the entire manufacturing operation from product design to fabrication and distribution can be seen as a major contribution to the productivity of the modern factory.

Flexible manufacturing systems complete a process of factory automation that started in the 50s.[4] The new systems incorporate computer-controlled machining centres that produce metal parts rapidly and with great precision, robots to handle these parts and remote-controlled carts to deliver the materials. Electronic controls link the various components and determine the procedures at the various stages of the manufacturing sequence.

The application of technological developments to mining and heavy industry not only raises productivity, but also has a pronounced effect on health and safety by freeing workers from dangerous tasks and reducing fatigue and boredom.

Factories can now be designed to allow for the employment of handicapped workers. Not only can facilities be designed or adapted to permit ease of access, but technological devices can compensate for an operator's loss of physical abilities. In Ontario, the Handicapped Employment Program encourages employers to explore applications of new technologies, job redesign, aids and adaptations to increase employment opportunities and productivity of disabled workers.

Computers help companies to meet air pollution control requirements, which have an immediate effect upon the working and neighbouring environment.

As health and safety legislation is strengthened, robotics can be used more and more to maintain production in circumstances where regulations will not permit exposure of human operators.

It is clear that health and safety conditions at work will be affected by the introduction of the new technology. Not only can micro-processors be used to create a more challenging and stimulating environment, but they can provide safer and healthier conditions for the work force. Unfortunately, we have to recognize that they bring with them their own peculiar set of health and safety problems.

Robots that are designed to remove workers from potentially dangerous situations can, themselves, become hazards if proper safety precautions are not taken. Industry must develop the necessary skills and techniques so that surprise robot action, through program or control system faults, cannot present a hazard to the human operator.

To date, there is only one recorded fatal accident involving a robot. A repair man was killed when he was struck by the operating arm of a robot at the Kawasaki Heavy Industries Plant near Tokyo.[5]

Manufacturers must be made aware of the need to build in safety at the system design stage and of the need for adequate safety equipment. According to a booklet produced by the U.K. Machine Tool Trades Association, entitled *Safeguarding Industrial Robots*, the most important safeguard of all is training.[6] No one should be allowed to work with a robot until adequately trained. Training is also particularly important for machine fault diagnosis and maintenance.

It has been suggested that one of the best ways to ensure the safety of workers is to enclose the entire work envelope so that no one can get into the robot's hazard area. It is difficult to guard specific areas near the robot's work envelope because the use of photoelectric cells and other devices usually makes it too complicated. A recent accident in an automotive plant in Ontario where a worker stepped into the path of a welding robot demonstrated the need for complete enclosure.[7] However, enclosing a robot will not eliminate all possibility of accident. Japanese and Swedish surveys have shown that only about 10 per cent of accidents involving robots occur during normal operation, and that greater risks occur during programming, teaching and maintenance. Ways must, therefore, be found to avoid having people work in the hazard area.

Other health effects associated with the use of advanced technology can add to the problems already existing in workplaces that are often not designed with ergonomic criteria in mind. A task force of the advisory council is currently attempting to evaluate the available information on the possible hazards to human health associated with the use of visual display units. In its study of ergonomic factors, the task force will assess the evidence for such health effects as discomfort, degradation of visual acuity and excessive fatigue. The task force has already submitted recommendations to the minister on the Electromagnetic Spectrum and Potential Reproductive Hazards.[8]

We have discussed some of the obvious and immediate safety, and, perhaps, health, hazards attendant upon the new technology. There are many other equally serious, but less obvious, factors to be considered that so far have been seen by many as having only an indirect bearing on occupational health and safety. Boredom and fatigue, for example, symptoms that can be associated with work in an automated environment, can result in operator errors that lead to injury and loss of life.

Technological development is already so far advanced that concerns are increasing about the possible social and economic impact of the race to improve productivity by industrial automation. Not the least of these is a concern for the psychological well-being of the work force, which will be faced with many social adjustments.

In Sweden, the *Work Environment Act* provides an example of legislation that takes into account the close connection between a worker's mental and social well-being and his or her general health and safety. A basic provision of the Act lays down that the working environment must be satisfactory in relation to the nature of the work and to social and technical developments. The work must be adapted to the physical and mental requirements of the individual.[9]

Labour Canada's Task Force on Micro-Electronics and Employment in its 1982 report *In the Chips: Opportunities, People, Partnerships* favoured a less restrictive view of the term 'health'.[10] It recommended that the *Canada Labour Code*, Part IV define occupational safety and health to accord with the definition endorsed by Canada at the International Labour Organization's 'Convention Concerning Occupational Safety and Health and the Working Environment' (1981). The definition is:

> . . . the term 'health' in relation to work indicates not merely the absence of disease or infirmity; it also indicates the physical and mental elements affecting health which are directly related to safety and hygiene at work.

If we are prepared to add such qualitative criteria to quantitative economic assessments of robot operations, we can design systems that not only increase efficiency, but also provide a satisfying and comfortable environment for the human operators. Such conditions contribute to the mental well-being of the work force and, on a practical level, have been shown to result in reduced sickness and absenteeism.

Government has a role to play here in equipping the individual, through the educational system, with the skills and attitudes needed to function harmoniously in this new environment.

By educating and training individuals and organizations in quality of working life approaches, the Ontario Quality of Working Life Centre, established by the Ontario government in 1978, seeks to fulfil its mandate, which is to promote and support the enhancement of the quality of working life of people in Ontario. The other two major areas of activity involve the initiation, implementation, monitoring and evaluation of quality of working life projects in joint union-management settings, and the creation, collection and dissemination of information on the subject. In 1981/82 the centre funded a study on microprocessor technology and its effects on the quality of working life.[11]

Some consider that the most significant social cost of increasing automation will be job displacement. Stress caused by changing conditions at work and uncertainty about the future take their toll in terms of the mental and physical elements that constitute good health. The employee who is under the constant threat of unemployment is likely to be neither a healthy nor a safe worker. Increased efforts must be made to combat these indirect health effects by assuring such employees of relocation and retraining opportunities.

The data on job loss as a result of automation give cause for concern. In Canada, the Institute for Research on Public Policy has addressed the question of present and foreseeable impacts of office automation on employment of women.[12] Pointing to the increasing divergence between, on the one hand, a growing supply of female clerical labour and, on the other, a rapidly collapsing clerical labour demand, the institute's report warns that, unless appropriate measures are taken, there could be nearly a million women without employment by 1990.

It is questionable how many jobs will be created in Canada in the microprocessor industry. It is likely that only highly trained personnel will be required in computer and associated industries. How many employment opportunities will arise from growth in the service industries is uncertain. Unfortunately, the statistical base has not yet been developed in Canada from which to assess the likely impact of technological change.

In Austria, studies aimed at producing projections of the impact that technological applications will have on industry over the next 10 years have already been undertaken.[13] The projections for 1990 indicate that, unless certain steps are taken, levels of unemployment largely due to job displacement will equal those of the 1930s.

In West Germany, the Minister of Research and Technology has brought together a Technology Policy Dialogue group consisting of representatives of science, private industry, unions and government.[14] As a result of the group's discussions, a new Technical Change and Employment Forum has been set up to increase awareness of the positive and negative employment and social impacts of micro-electronics and related technologies in the workplace.

Not only will the size of the work force be affected by the introduction of advanced technology. A significant factor to be borne in mind in assessing the future impact of technological change is the likely reduction in the size and strength of the union movement in many industrial sectors because of increasing unemployment and dwindling membership. Such a reduction in the strength of organized labour could represent a serious loss to the cause of occupational health and safety if limited resources diminish, in any way, labour's valuable contribution in this area.

It is generally recognized that technological progress can provide new opportunities for social choice. However, there is a growing concern that rather than ensuring that social and economic goals and priorities govern the application of new knowledge and technological developments, we may allow the application of the new knowledge to occur without consideration of its impact on the social and cultural values that are important to our society. Because the response of society to major change in the past has been reactive rather than proactive, there are many examples of technological development resulting in adjustments that were not beneficial to society as a whole. It is worth reflecting that the changes brought about by the industrial revolution were detrimental to many, at least in the short-term, although they have ultimately provided benefits to a large sector of the population in developed countries. It is to be hoped that in anticipating the problems ahead we can respond to the challenge in such a way as to minimize the detrimental effects of unplanned and precipitous change.

The criticism may be levelled that such broad social issues do not come within the purview of an advisory council on occupational health and occupational safety. It is clear, however, that council has a responsibility to examine the health and safety implications of the new technology. In so doing, it must enquire into the impact on health of such closely related socio-economic factors as job displacement. Individuals in the lower socio-economic groups are the most disadvantaged as far as health is concerned.[15] There is evidence that when unemployment increases with correspondening adjustments in society, mortality also increases.[16] Thus, council and any other body concerned with the general well-being of the population and, more specifically, of the members of the work force, cannot afford to ignore the application of advanced technology that will have a direct impact upon the working environment and the quality of human life.

If public policy is to aim at securing safe and healthy work environments and reducing the inequalities in human health without unduly obstructing technological progress, certain adjustments and new initiatives will be required in those institutions that guide and influence social change. Close co-operation between management, labour and government will be required to establish a common goal and to agree upon a method for achieving it. The philosophy of combined responsibility of management, labour and government in matters of health and safety, upon which the *Occupational Health and Safety Act* is founded, may provide the basis for a common approach. If this is to succeed, however, it will be necessary to provide all parties with an opportunity to impact upon the policy decisions with respect to the use and implementation of advanced technology in the workplace.

An opportunity to be heard will not be sufficient in itself. Both labour and management will need the assurance that when they are asked to speak on an issue, they will have the financial and other resources available to ensure that their proposals are based upon sound research and expert opinion.

What fiscal arrangements and institutional structures will we need to put in place to bring about the necessary understanding and purposeful co-operation between all the parties affected by these changes? This was just one of the considerations that council had in mind when it decided to open the discussion on the role of government in this rapidly changing occupational scene.

The Role of Government

In several of its advisory memoranda to the minister over the past five years—notably in Advisory Memorandum 80-IV, which dealt with Policies and Principles for the Use of Information in the Prevention of Occupational Accidents and Illnesses,—council has addressed the theme of co-ordination of resources, data and regulatory procedures in the area of occupational health and safety.[17]

In 1978, with the enactment of the *Occupational Health and Safety Act*, the groundwork was laid for the establishment of a rational and co-ordinated administrative structure. The historic problem of divided jurisdiction and responsibility was addressed and, in placing responsibility for occupational health and safety with the Ministry of Labour, some progress was made toward eliminating the fragmentation of authority, which is still seen, for example, in the federal jurisdiction and in those areas where federal and provincial jurisdictions overlap.

Council has recently started to assess the procedures involved in the development and promulgation of the designated substance regulations. In so doing, it has become acutely aware of three factors: 1) the rapidly increasing need on the part of industry, in a technologically complex environment, for sophisticated data and, in many areas, very detailed guidance that will enable it to take on the responsibility of internal self-regulation; 2) the ever increasing pressures that are placed on the Occupational Health and Safety Division of the ministry, whose responsibility it is to provide many of the research and evaluation services without which industry cannot be expected to implement the goals set for it by the Act and regulations; and 3) the natural limitations placed upon an advisory council in attempting to implement a joint labour/management approach to occupational health and safety matters.

While acknowledging the significant achievements of the Occupational Health and Safety Division to date, council feels that it is not inappropriate to ask the question: Will our arrangements for occupational health and safety be suitable in dealing with the ever-increasing complexity of the industrial/technological scene? More specifically, are these present arrangements conducive to a co-operative approach to the issues, and does the administrative framework enable us to deal with the question of equalization of resources so as to guarantee that all the parties have a significant input into decisions?

Council proposes to open the debate on the subject of the most appropriate structures in the area of occupational health and safety in Ontario in the coming years by looking at some alternative arrangements that are being tried in other provinces and in the United Kingdom and Europe. It should be emphasized here that council is not advocating a change to some similar arrangement in Ontario. Rather, it proposes to listen attentively to all who wish to comment on these ideas before attempting to reach any conclusions of its own about possible future developments.

Three Canadian provinces have started moving in the direction of a single administration for all occupational health and safety related services.

In March 1979, the Alberta Department of Labour, Occupational Health and Safety Divison, became part of the newly-formed Workers' Health, Safety and Compensation Department, which reports through the Minister Responsible for Workers' Health, Safety and Compensation. The department is divided into two sections: The Workers' Compensation Board and the Occupational Health and Safety Division. The Occupational Health and Safety Division functions very much like a regular government department, with a chief executive officer whose duties are similar to those of a deputy minister.

Quebec's Commission de la Santé et de la Sécurité du Travail was established in the spring of 1980, replacing the Commission des Accidents du Travail du Québec. With a triple mandate for prevention, inspection and compensation, it assumes full responsibility for implementing the province's occupational health and safety program.

The commission is administered by a board of directors, composed of representatives of labour and management, chosen from lists submitted by employers' associations and union associations. In addition, the government appoints the chairman and vice-chairmen. The chairman at present reports to the Ministre d'Etat au Développement Social.

In June 1980, the *New Brunswick Occupational Health and Safety Commission Act* was passed. The Act established the New Brunswick Occupational Health and Safety Commission, which was to assume primary responsibility for the administration of the *Occupational Safety Act*. The commission, made up of representatives of labour and management with a full-time chairman appointed by government, reports to the Minister of Labour and Manpower.

At the same time, the *Workmen's Compensation Act* Amendment eliminated the funding provisions for employers' associations to promote accident prevention, a function which was to be taken over by the commission.

In 1974, the British government acted on the advice of the Robens Committee in establishing the Health and Safety Commission, an independent commission responsible for all occupational health and safety matters.[18] In order to ensure that it had a recognizable separate identity, and that it should be able to establish its authority clearly and unequivocally, the Robens Committee recommended that the commission not be located inside a government department.

Pursuant to the recommendations of the committee, 'user interests' (i.e. unions, employers and local authorities) are represented on the Managing Board. The commission reports to the Secretary of State for Employment, who issues the necessary regulations on advice given him by the commission.

In Sweden, the National Board of Occupational Safety and Health reports directly to Parliament. Although the board is appointed by the government, its regulations cannot be changed or challenged by it. It consists of a Director-General, his or her deputy, representatives of unions and employers, together with two members of Parliament and two civil servants. It has full responsibility in the areas of prevention, research, training and inspection.

Viewed in the context of a discussion of the rapid technological development in industry and its implications for the work force, the institutional arrangements that have been outlined have characteristics that may be important for the future. There appears to be an advantage in establishing bodies that have representatives of all the parties affected by technological change to provide input into decisions on broad health-related issues. Such an arrangement might allow us a better understanding of the technological changes that would be acceptable to both management and labour, and enable us to adopt policies aimed at avoiding those changes that are not beneficial to the overall work force and population.

It would not be an easy task to set up an independent authority for occupational health and safety with a joint management/labour board. Many factors would have to be taken into consideration, including the possibility that a structure that is seen by many to be working well might be irretrievably damaged. In opening the debate on the subject, council offers these additional points for discussion:

- There may be a reluctance in some sectors of management and labour to depart from the traditional adversarial approach.
- Separation from the direct political process may be seen to involve loss of government control.

- The body charged with regulatory responsibility would no longer be held directly accountable to the electorate for its decisions, although it would be ultimately accountable to the legislature, through its board.
- It might be difficult to ensure appropriate representation of those groups, such as small businessmen, which, at the present time, are not necessarily part of a formal provincially or nationally based organization and which must rely upon their ability to make their voices heard at the political level.
- Similar difficulties might arise in ensuring effective labour participation due to the fact that only part of the labour force is organized.
- Labour and management co-operation would be essential.
- There may be disputes about how management and labour representatives should be chosen, particularly because of our present organizational arrangements.

Against these legitimate concerns, the following potential advantages should be weighed:

- A single body, governed by a joint labour and management board, charged with responsibility for all occupational health and safety matters could eliminate duplication and encourage co-operation not only between government departments, but also between the various non-governmental participants in the occupational health and safety field.
- An independent body governed by a joint labour and management board can facilitate the effective involvement of management and labour not only in the standard-setting process, but also in the day-to-day administration of health and safety legislation.
- Such a board or commission with joint representation can create arrangements that enhance the shared responsibility and accountability approach at the operating level.
- In removing responsibility for occupational health and safety from a ministry that is primarily concerned with labour relations matters, some would argue that the non-adversarial character of health and safety is given appropriate emphasis. A means might thereby be found of capturing the strengths of the bargaining process while, at the same time, avoiding some of its weaknesses.
- A board or commission that is not part of a government ministry can provide a forum in which labour and management can resolve issues jointly and where the likelihood that either party will seek to promote its position through the partisan political process is greatly reduced.
- An independent body can establish its own career structures to provide high calibre professionals with career advancement possibilities tied to the specific purposes of the organization. Such an independent body would give a high profile to occupational health and safety concerns and to professional careers in this field.
- A body with exclusive jurisdiction in occupational health and safety matters could take on responsibility for joint management and labour training programs.

Implications for the Advisory Council

Among the factors that would have to be considered in any debate on the merits of a separate/independent authority in the field of occupational health and safety would be the following:

1) the need to ensure the most efficient use of resources to avoid duplication and to co-ordinate the efforts of the various government branches, agencies and other organizations in this field;
2) the need to ensure that labour and management input occurs at the most appropriate stage in the decision-making process.

Any judgment, therefore, on the question of a separate/independent occupational health and safety authority would have to include an assessment of council's own role, and a decision about whether council itself should continue to exist or whether, in light of the above two considerations, its function might more appropriately be taken over by the new body. It could be argued, for example, that industrial and labour interests should be directly involved in the board or commission, with full responsibility and accountability for policy and programs in occupational health and safety, rather than perform their present advisory role.

Conclusion

Council urges all those involved in the field of occupational health and safety to give serious and immediate consideration to the impact that technological development will have on the health and safety of the work force and to the indirect effects these changes will produce on the health and general well-being of Canadians.

In a recent article on The Distribution of Work and Income, Wassily W. Leontiff[19] discussed the profound challenge that an advanced industrial society must now begin to face under the impact of the continuing Industrial Revolution. He concluded with the following very significant comments:

> History, even recent history, shows that societies have responded to such challenge with revision of their economic institutions and values conducive to the efficient use of changing technology and to securing its advantages for popular well-being. History shows also societies that have failed to respond and have succumbed to economic stagnation and increasing social disorder.

Footnotes

1. Advisory Council on Occupational Health and Occupational Safety, Fourth Annual Report, April 1, 1981 to March 31, 1982, Introduction, pp. 13 to 23.
2. Marovelli, Robert L. and Karhnak, John M., The Mechanization of Mining. Scientific American, vol. 247, no. 3, September 1982, p. 90.
3. Gunn, Thomas G., The Mechanization of Design and Manufacturing. Scientific American, vol. 247, no. 3, September 1982, p. 114.
4. Bylinsky, Gene, The Race to the Automatic Factory. Fortune, February 21, 1983.
5. Medical Post, vol. 18, no. 12, June 15, 1982, p. 61.
6. Safeguarding Industrial Robots, Part 1, Basic Principles, Machine Tool Trades Association, London, 1982.
7. Globe and Mail, February 10, 1983.
8. Advisory Council on Occupational Health and Occupational Safety, Fifth Annual Report, April 1, 1982 to March 31, 1983, Advisory Memorandum 82-VI on Interim Recommendations on the Electromagnetic

Spectrum and the Potential Reproductive Hazards of Visual Display Units, February 25, 1983, p. 195.

9. Danielson, Gunnar, Work Environment Legislation, Standard and Enforcement Practices in Sweden, National Board of Occupational Safety and Health, Stockholm. Paper presented to Royal Commission on Matters of Health and Safety Arising from the Use of Asbestos in Ontario, Toronto, 1982.
10. In the Chips: Opportunities, People, Partnerships. Report of the Labour Canada Task Force on Micro-Electronics and Employment, Ottawa, Government of Canada, 1982, p. 13.
11. As yet unpublished study.
12. Menzies, Heather, Women and the Chip: Case Studies of the Effects of Informatics on Employment in Canada. The Institute for Research on Public Policy, Montreal, 1981.
13. Leontief, Wassily W., The Distribution of Work and Income. Scientific American, vol. 247, no. 3, September 1982, p. 188.
14. Schafer, Joachim, The West German Perspective. CIPS Review, January/February 1980, p. 29.
15. Wilkins, Russell, Health Status in Canada, 1926-1976, Institute for Research on Public Policy, Occasional Paper No. 13, May 1980.
16. Brenner, M.H., Mortality and the national economy: A review, and the experience of England and Wales, 1936-1976. Lancet, 2:568, 1979.
17. Advisory Council on Occupational Health and Occupational Safety, Third Annual Report, April 1, 1980 to March 31, 1981, Advisory Memorandum 80-IV on Policies and Principles for the Use of Information in the Prevention of Occupational Accidents and Illnesses, p. 162.
18. Safety and Health at Work, Report of the Committee 1970-72, Chairman Lord Robens, London: HMSO, 1972.
19. *Op. Cit.*

COUNCIL'S ADVISORY MEMORANDA

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Advisory Council on
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April 20, 1982

The Hon. R.H. Ramsay
Minister of Labour
400 University Avenue
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Dear Mr. Minister:

On behalf of the Advisory Council, I am enclosing Advisory Memorandum 82-I in which Council has reviewed the process for the development of the vinyl chloride regulation, in light of the policies and principles set out in Advisory Memorandum 78-II.

Council is pleased to have participated in the process by which the final vinyl chloride regulation was developed.

Yours truly

J.F. Mustard, M.D.
Chairman

Encl:

cc: Mr. T.E. Armstrong
Dr. A.E. Robinson

Advisory Memorandum 82-I to the Minister of Labour

April 20, 1982

A Review by the Advisory Council of the Process Used to Develop a Standard for Vinyl Chloride and Council's Evaluation of the Criteria Utilized to Assess the Hazard of Vinyl Chloride Exposure in the Workplace

INTRODUCTION

In February 1978, the advisory council and the then Minister of Labour agreed that council should be given the task of reviewing the principles and procedures used in setting occupational health standards and guidelines in Ontario. In Advisory Memorandum 78-II, council set out a list of the basic principles and procedures that should ideally characterize the policy process in respect to establishing standards, guidelines and codes. In this document, council undertook to review the criteria utilized by the Ministry of Labour to evaluate occupational health hazards and to follow the ministry's standard setting process through to its final form. It was also clearly understood that council would limit its review to the process leading to the development of ministry standards. In its memorandum, council also stated that it would require 30 days to complete its review function. In subsequent correspondence with the minister, it was agreed that, because of public interest in the area, council's review of the standard setting process should be submitted in the form of an advisory memorandum.

In June 1980, the Ministry of Labour published a Notice of Intent to designate vinyl chloride as a substance 'to which the exposure of a worker is prohibited, regulated, restricted, limited or controlled under the *Occupational Health and Safety Act.*' This was followed, in August 1980, by a notice setting forth the ministry's proposed regulation for vinyl chloride. The notice invited public comments and stipulated that such comments would be made available for public examination. At the same time, the ministry distributed copies of the proposed regulation and two accompanying codes to interested members of the public. In October 1980, the ministry distributed a document entitled *Interim Report on the Designation of Vinyl Chloride in Ontario.* This document dealt with such topics as the use of vinyl chloride in Ontario, workplace exposures to vinyl chloride, the control of such exposures and the health effects of vinyl chloride. Each interim report also contained a copy of the proposed regulation and codes. On June 9, 1981, the ministry held a public meeting to discuss changes that had been made to the August 1980 version of the regulation. A revised version of the proposed regulation and accompanying codes were distributed at this time, along with an entirely new Code for Medical Surveillance for Vinyl Chloride. Invitees were told that they would have a short period of time to comment on any revisions that had been made to the regulation and codes.

On August 14, 1981, the ministry submitted to council a revised version of the vinyl chloride regulation, subject to any amendments that might be made as a result of submissions made by the public after the June 9 meeting. Included with the regulation was a document entitled *The Report on the Designation of Vinyl Chloride in Ontario.* This document contained, among other things, a summary of the views expressed by members of the public on the various provisions contained in the first and second drafts of the regulation. The type of action taken by the ministry in response to the submissions made was also outlined. The background materials supplied to council did not contain an analysis of the type of economic impact that Ontario industry would likely experience if the provisions contained in the proposed vinyl chloride regulation were implemented.

After an initial review of the revised regulation and accompanying background materials, council asked that a meeting be scheduled between its Task Force on Regulations and ministry officials. The objective of this meeting was to permit task force members to explore, in greater depth, the rationale employed by the ministry to arrive at certain policy decisions. The meeting in question took place on November 16, 1981. The agenda for discussion, which was prepared for this meeting, is reproduced in Appendix 1 of this advisory memorandum.

On February 12, 1982, the Minister of Labour transmitted to council a letter which set out a number of amendments that had been made to the vinyl chloride regulation and to the Code for Medical Surveillance for Vinyl Chloride. Some of these changes had been recommended by council, while others were the product of the ministry's discussions with other groups. A copy of the final draft regulation and the three accompanying codes were also supplied at this time. The minister's letter of February 12, 1982 is attached as Appendix 2.

As was the case in council's review of the process leading to the development of the lead and mercury regulations, council intends to focus on three aspects of the standard setting process. These are the consultative process (i.e. whether the public was provided with sufficient opportunity to comment upon and participate in the development of the regulation), the analytical process (i.e. whether the ministry assembled, reviewed and analysed the available evidence in a reasonable fashion, and whether the conclusions reached were compatible with the evidence) and the legal-technical process (i.e. whether the regulation and codes are internally consistent, and whether the intent of the ministry is expressed in a clear and unambiguous fashion).

COUNCIL'S REVIEW OF THE STANDARD SETTING PROCESS FOR VINYL CHLORIDE

1. The Consultative Process

To reiterate the comments made in Advisory Memorandum 81-I on lead and Advisory Memorandum 81-III on mercury, council wishes to commend the ministry for the steps it has taken to make possible public participation in the consultative process for the development of occupational health regulations. Council strongly endorses the ministry's efforts to develop an open process for the setting of standards. Council is also cognizant of the special circumstances that surrounded the publication of the first seven designated substances regulations and the difficulty of adhering strictly to the procedures set out by council in Advisory Memorandum 78-II. In this regard, council notes that the Minister of Labour has undertaken, in his reply to

Advisory Memorandum 81-I, to give serious consideration to a number of suggestions made by council to enhance the quality of the consultative process.

In Advisory Memorandum 81-III, council raised what it considered to be a particularly important point relating to the consultative process for the development of occupational health regulations. Council wished to know why the ministry had taken the position that only the final version of a designated substances regulation, and not the accompanying codes, should be published in the *Ontario Gazette*. In response, it was stated that the custom and practice of the Legislative Counsel and the Office of the Registrar of Regulations is to publish regulations without referenced materials and that this practice will continue. While council notes that procedural constraints exist, it wishes to emphasize that the codes contain several extremely important provisions and, therefore, ought to be made subject to the normal gazetting process, if at all possible. As a potential solution to this problem, council suggests that the codes be reclassified as schedules, to follow the same format as Schedule 2 of the Proposed Regulation for Coke Oven Emissions.

2. The Analytical Process

Council's review of the analytical process employed by the ministry to develop a standard for vinyl chloride is made particularly difficult for two reasons. First, vinyl chloride is a known carcinogen. Second, epidemiological data of an acceptable quality are not available to provide guidance on the choice of an appropriate strategy for the control of the substance. It is in this climate of uncertainty that council must review the process by which the ministry has analysed the available scientific, economic and technical information, and determine whether the conclusions reached are compatible with the evidence reviewed.

a) *The Ministry's Rationale for Establishing a Time-Weighted Average Exposure Limit (TWAEL) for Vinyl Chloride at Two Parts Vinyl Chloride per One Million Parts Air (two ppm)*

The ministry's documentation indicates clearly that vinyl chloride is a known carcinogen which has been associated with tumour development in both animals and man. Treating vinyl chloride in this fashion, the ministry thought it desirable to develop a dose-response curve for vinyl chloride exposure in humans. After reviewing the scientific literature, however, the ministry concluded that such a curve could not be fashioned from the available epidemiological data. On that basis, a decision was made to utilize animal data in order to formulate a dose-response relationship for man. The ministry then determined that the experiments conducted by Maltoni[1] on Sprague-Dawley rats were the only ones that could be employed to accomplish this objective.

The rats used in the Maltoni study were divided into six exposure groups and one control group. Rats in each of the exposure groups were subjected to a different level of vinyl chloride (i.e. 50, 250, 500, 2,500, 6,000 and 10,000 ppm) for a period of 52 weeks. Complex extrapolation procedures were then applied to the experimental data in an attempt to measure the health risks to rats at exposure levels lower than those employed in the experiments. Finally, the low dose calculations obtained in rats through this procedure were extrapolated directly to humans in order to develop a dose-response relationship for man.

On the basis of extrapolations from the Maltoni data and taking into account the estimated exposure to vinyl chloride of a worker continuously exposed to the substance over a working lifetime, the ministry concluded that, at a one ppm exposure level, up to 24 excess tumours per year per 100,000 workers could be produced as a result of occupational exposure to vinyl chloride. The ministry then compared this risk estimate to the annual level of acceptable risk proposed by the International Commission on Radiological Protection (ICRP) for workers exposed to ionizing radiation. The ICRP calculated this acceptable risk to be 50 deaths per year per 100,000 workers.[2] The ministry then took the position that the ICRP level of acceptable risk should be applied to vinyl chloride workers in Ontario. In this respect, it was concluded that a two ppm exposure level for vinyl chloride might theoretically lead to 50 excess tumours per year per 100,000 workers; and the decision was taken to set the Time- Weighted Average Exposure Limit at this point.[3]

In the background materials supplied to council, the ministry acknowledges that its calculation of an acceptable level of exposure for vinyl chloride hinges on the validity of certain key assumptions. In council's view, the most important of these assumptions are:

i) There does not exist a threshold level of exposure to vinyl chloride below which carcinogenic effects will be absent.
ii) Tumour risk increases in proportion to exposure dose (i.e. the dose-response relationship is linear).
iii) The lifetime tumour risks in man and in Sprague-Dawley rats are the same, provided that the same proportion of each species' average lifetime is spent exposed to the same concentration of vinyl chloride.
iv) The health effects observed at high doses in one species can be extrapolated directly to lower doses in the same species.
v) It is possible to extrapolate health effects quantitatively from animals to humans.

As indicated in the background documentation, there exists considerable uncertainty within the scientific community on the weight that should be accorded to any of these assumptions in establishing control levels for carcinogens.

b) *The Process of Risk Assessment Employed by the Ministry*

It is clear that the ministry faced a difficult task in setting a Time-Weighted Average Exposure Limit for vinyl chloride. Essentially, the ministry had two options available to it: a) follow the approach adopted by the US Occupational Health and Safety Administration (OSHA) and regulate vinyl chloride exposures at the lowest feasible level,[4] or b) employ a process of risk assessment as a basis for selecting a control level. The ministry, in adopting the second strategy, was, of necessity, required to choose some level of acceptable risk. As indicated, the risk level selected was the ICRP figure of 50 excess tumours per year per 100,000 workers. In this respect, council notes that the background materials supplied by the ministry did not contain a discussion of the rationale employed for adopting this level of risk as opposed to others. In addition, council has not seen any evidence of dialogue between the ministry and members of the public on the suitability of the risk level that has been chosen. Council is surprised that at least some organizations did not address the question of acceptable risk and is concerned about the apparent lack of debate on this important topic. In order to ensure that all interested parties understand the implications of the ministry's 50 excess tumour risk policy for vinyl chloride, council suggests that the minister give consideration to the option of holding further public discussions on this issue.

c) *The Ministry's Application of the ICRP's Model for the Control of Hazardous Exposures*

In reviewing the manner in which the ministry has applied the ICRP's model for the control of hazardous exposures, council is concerned that one component of the model (i.e. acceptable risk) has been stressed while other key elements have not been similarly emphasized. According to council's understanding, the ICRP approach consists of three basic principles:

i) The justification principle (i.e. individuals must not be exposed to harmful agents unless the exposure is justified by the benefits that are conferred on society as a result of the agents' use).
ii) The ALARA principle (i.e. all exposures must be kept as low as reasonably achievable, economic and social factors being taken into account).
iii) The stipulation that, irrespective of (ii) above, the exposure to individuals must not exceed a maximum permissible limit to be recommended by the ICRP.[5]

In short, while the ICRP approach enjoins employers to strive for stringent control levels, maximum permissible exposure limits have also been set out. The ceiling limits chosen (which are rarely approached in practice) are designed to ensure that the excess cancer risk attributable to ionizing radiation among exposed workers does not exceed 50 tumours per 100,000 workers per year. This estimate of excess risk is based on the assumption that the average exposure of a radiation worker will be at the ceiling level. It must be emphasized, however, that where the ICRP model has been adopted in Canada (e.g. at the nuclear generating sites run by Atomic Energy Canada and by Ontario Hydro), the annual radiation dose received by an average atomic radiation employee regularly exposed to ionizing radiation, is about one-tenth the ceiling value.[6] In effect, employers in the nuclear field have chosen to accept an average level of exposure that yields an excess risk of approximately 5 deaths per 100,000 workers per year. On the other hand, a level of risk of 50 deaths per 100,000 workers per year has been used to establish a two ppm TWAEL for vinyl chloride. On the assumption that the extrapolations from the Maltoni data are correct, this means that workers exposed to vinyl chloride may be, on the average, 10 times more likely to contract an occupationally induced cancer than workers exposed to ionizing radiation in Ontario nuclear facilities.

d) *The Decision to Calculate Time-Weighted Average Exposure Limits over a 40-Hour Sampling Period*

During their meeting with ministry officials, members of the Task Force on Regulations asked why the decision had been made to calculate TWAELs over a 40-hour period, rather than over the customary 8-hour period. In response to this point, the ministry indicated that, irrespective of vinyl chloride's potential carcinogenic properties, chronic health effects should not arise in workers where the two ppm TWAEL is calculated over a 40-hour period, provided that the 10 ppm maximum exposure limit (MEL) is not exceeded.

Council recognizes that the choice of a 40-hour sampling period provides an enormous administrative convenience for employers whose operations do not run on standard 8-hour shifts. Some members of council believe, in addition, that at low levels of exposure, it does not matter whether sampling takes place over an 8 or 40-hour period. Other members feel very strongly, however, that, given i) the uncertainties inherent in the process of carcinogenesis and ii) the yet unresolved issue of whether prolonged exposures at or around the maximum exposure level might be more likely to induce cell proliferation, the 8-hour sampling period would provide an extra margin of safety.

e) *The Effects of Vinyl Chloride on Germ Cells (i.e. Sperm and Ova)*

In the ministry's background materials, it is stated that an association may exist between exposure to vinyl chloride and the incidence of congenital abnormalities in the offspring of exposed populations. In this respect, task force members wished to know why the ministry had not placed a warning in the Code for Medical Surveillance for Vinyl Chloride to the effect that exposure to females of childbearing age should be kept to a minimum. In response to this concern, ministry officials indicated that, although there exists some evidence to suggest that vinyl chloride may have an effect on the sperm and ova, the evidence is of a poor quality. The ministry stated, furthermore, that where there is clear evidence of risk to the unborn fetus, appropriate regulatory action will be taken. In the case of vinyl chloride, however, it was felt that the available evidence on germ cell effects was not strong enough to warrant the inclusion of a specific warning in the code.

Council would note, at this point, that there are biological reasons to suspect that vinyl chloride could affect germ cells. Until such time as better studies are available on this subject, council believes that caution should be exercised.

f) *The Application of the Vinyl Chloride Regulation to 'On-Site' Construction Workers*

Sub-section 3(2) of the draft vinyl chloride regulation originally reviewed by council provided that every employer to whom the regulation applies shall comply with sections 4 and 5 of the regulation in respect to all workers who perform construction tasks in the employer's workplace, irrespective of whether these construction workers are the actual employees of the employer. Sections 4 and 5 deal respectively with the maintenance of exposure limits and the use of personal protective equipment.

In the most recent draft of the vinyl chloride regulation, however, several important amendments have been made to section 3. Sub-section 3(3) now provides that constructors or employers carrying out construction projects (rather than worksite employers) will be responsible for ensuring that the health of on-site construction workers will be protected from the effects of vinyl chloride exposure. This will mean, for example, that where a construction worker employed by a constructor comes onto a worksite where a vinyl chloride control program is already in place, the elements of the control program will presumably not apply to the worker. Instead, the constructor will be required to devise a suitable control program for his own workers. In contrast to this position, sub-section 3(2) of the amended regulation provides that the worksite employer is the individual who must protect the health of all other classes of on-site workers (e.g. maintenance personnel on contract) who might come into contact with vinyl chloride at the worksite.

Since the ministry did not provide council with a rationale for the changes that have been made, it is difficult for council to comment on the soundness of the analytical process upon which the amendments were based. Council wishes to observe, however, that in making constructors, rather than worksite employers, responsible for the health of on-site construction workers who are exposed to vinyl chloride, a heavy burden is being placed on the former group. Council wonders, in this respect, how the ministry will ensure that constructors are suitably appraised of i) the health risks posed by exposure to vinyl chloride, and ii) the measures that must be implemented to control such exposures.

Council also wishes to note that, until such time as a general designated substances regulation is enacted for the construction industry, constructors will not be obliged to take any specific steps to minimize worker exposure to vinyl chloride. While council appreciates that sub-section 13(1)(a) of the *Occupational Health and Safety Act* imposes a general duty on constructors to protect the health and safety of workers, it is a matter of urgency, in council's view, that specific provisions be enacted to control the exposure of construction workers to vinyl chloride and to other designated substances.

g) *The Economic and Technological Feasibility of Achieving Lower Control Levels for Vinyl Chloride Exposure*

During their meeting with ministry officials, task force members asked whether the one ppm level for exposure to vinyl chloride currently in force in the United States was both technologically and economically feasible for Ontario industry. On the subject of technological feasibility, ministry officials indicated that most of the vinyl chloride industry in Ontario is already, on the average, below one ppm. Ministry representatives stated, furthermore, that 'what we have is a regulation setting a minimal standard and, in fact, the industry is doing better on an informal basis.[6] The ministry's concern, however, was that it would be difficult for all vinyl chloride producers and users to maintain these low levels of exposure on a consistent basis. While council appreciates this concern, it notes that the policy approach adopted by the ministry raises the question of whether it is desirable to select exposure levels that are in excess of what some firms in the province are already achieving.

On the question of whether the US exposure standard would be economically feasible in Ontario, ministry officials indicated that an effort to achieve the one ppm exposure level (or better) on a regular basis would be very difficult for economic reasons. Council is still left with some uncertainty on this point, however, for the following reasons: i) the background materials supplied by the ministry did not address the issue of economic feasibility, ii) some Ontario companies have managed to control vinyl chloride exposures below the one ppm level, and iii) information obtained from some authorities in the United States indicates that the one ppm level is economically feasible.[7]

3. The Legal-Technical Process

As a result of discussions held between the ministry and interested groups, including council, subsequent to the June 9 public meeting, several amendments have been made to the vinyl chloride regulation and to the accompanying Code for Medical Surveillance for Vinyl Chloride. These changes are clearly beneficial and exemplify the value of the consultative process. The major amendments are set out below:

i) Sub-section 16(1) of the regulation has been amended to provide that a worker may only be declared unfit to work with vinyl chloride if this unfitness has arisen as a result of exposure to vinyl chloride. (The previous version of the sub-section had left open the possibility that a worker could be declared unfit for work for a reason totally unrelated to occupational exposures).

ii) Sub-section 16(2) of the regulation now provides that a vinyl chloride employee's entitlement to workmen's compensation benefits will be limited to those situations where the worker may have or has a condition resulting from the inhalation or absorption of vinyl chloride. (The previous version of the sub-section left the mistaken impression that a worker could be entitled to compensation, notwithstanding that his condition arose from causes unrelated to the working environment).

iii) Sub-section 4(1) of the Code for Medical Surveillance for Vinyl Chloride now specifies that a physician must make a decision with respect to when a worker who has previously been removed from a vinyl chloride worksite may be permitted to return to work.

iv) Sub-section 4(1) of the Code for Medical Surveillance for Vinyl Chloride no longer specifies that a worker must be removed from a vinyl chloride worksite when one or two liver function tests show abnormal results. Instead, a physician is now given the discretion to determine whether a removal is warranted on the basis of test results. In this regard, both ministry officials and council members agreed that, since liver function tests are not specific to vinyl chloride exposure, they should not be used as the sole criterion to determine when a worker should be removed from a vinyl chloride environment.

Council wishes to make several additional points in respect to the legal-technical process. Council believes that the following items require further clarification or comment.

a) *The Meaning of the Term 'Personal Records of the Exposure of a Worker', as Contained in Sub-section 7(2)(c) of the Regulation*

In the background materials supplied to council, several respondents asked the ministry to elaborate on the meaning of the term 'personal records of the exposure of a worker'. In this respect, task force members posed the following questions to ministry officials: i) Can the results of area monitoring be substituted for the results of personal monitoring? (answer—Yes); ii) Can the results obtained from monitoring worker (X) also be recorded for worker (Y) if both workers have the same job classification? (answer—Yes, provided that the workers are employed in the same job area); and iii) How often should monitoring for vinyl chloride be conducted? (answer—This is a matter for negotiation between management and the joint health and safety committee).

b) *The Type of Information that Must be Recorded for Workers Who Wear Respiratory Equipment on a Voluntary Basis*

During the meeting of November 16, task force members wished to know whether the voluntary use by workers of respiratory equipment must be recorded in exposure records. From the ministry's reply, council gathers that, although the recording of such information would be useful for epidemiological purposes, it has not been made a requirement under the regulation.

Council wishes to make the observation that, for the purpose of maintaining exposure data suitable for use in epidemiological studies, the distinction between the mandatory and voluntary use of respiratory equipment is artificial. Exposure records are designed to indicate, as accurately as possible, the amount of a hazardous substance to which a worker is exposed. Where the use of a respirator reduces the exposure level that would otherwise be recorded for a worker, this information is crucial for epidemiological purposes. This statement applies with particular emphasis to the study of workplace carcinogens where the quality of exposure data has traditionally been poor. In this respect, council wonders whether the ministry might reconsider its decision not to require that the voluntary use of respiratory equipment be recorded.

Some members of council have also made the suggestion that, unless a minimum reliable protection factor for a respirator can be established, the exposure level recorded for a worker who wears such equipment should be the same as that obtained through normal personal monitoring techniques.

c) *The Medical Removal and Subsequent Return of a Worker to a Vinyl Chloride Worksite*

During the meeting of November 16, 1981, task force members discussed with ministry officials the general topic of fitness for work. One of the questions considered was the following: What would occur in the situation where the physician in charge of a firm's medical surveillance program and a worker's family physician disagreed on the subject of i) whether the worker should be removed from a vinyl chloride worksite, or ii) once removed, whether the worker should be permitted to return. to work? The ministry's general view appeared to be that, once the physicians had consulted on the matter, any disagreements would be resolved. While council believes that this approach is proper, it wonders whether ministry medical staff would be prepared to offer their assistance in a situation where agreement cannot be reached.

d) *The Wording of Sub-section 4(1) of The Code for Medical Surveillance for Vinyl Chloride*

By virtue of sub-section 16(1) of the regulation, a physician who conducts a physical examination or clinical test on a worker is required to decide whether the worker is fit, fit with limitations or unfit to work with vinyl chloride. By contrast, sub-section 4(1) of the code provides that 'if the abnormality is confirmed, a decision *should* [emphasis added] be made by the physician as to whether the worker should be removed from vinyl chloride exposure.' For the sake of consistency, council suggests that the word 'should' be changed to 'must'.

CONCLUSION

In previous advisory memoranda, council has observed that the development of occupational health regulations is a difficult and complex task, particularly in the context of an open consultative process. In the case of the proposed vinyl chloride standard, it is clear that the dialogue conducted between the ministry and members of the public has caused important changes to be made to the regulation and accompanying codes. Council must also applaud the open attitude taken by ministry officials with respect to the points raised by its Task Force on Regulations.

Council notes that vinyl chloride is the first workplace carcinogen to be regulated as a designated substance. In this respect, the ministry has chosen to adopt an acceptable risk strategy as the basis for setting control levels for workers exposed to the substance. The ministry has concluded that an acceptable level of risk for vinyl chloride exposure is 50 excess tumours per 100,000 workers per year. This risk level was taken from the recommendations of the International Commission on Radiological Protection. While the ministry has set out clearly what it considers to be an acceptable level of risk, the background documentation provided to council does not discuss the rationale for the ministry's choice of this level as opposed to others. Although council recognizes that decisions about workplace health risks must ultimately be made at the political level, it is still desirable, in an open consultative process, that available policy options be fully discussed. It is also apparent to council, from a review of both the background materials and the minutes of the June 9 public meeting, that the ministry's approach to the subject of acceptable risk has not been debated. Council finds this lack of discussion curious since the briefs presented by labour organizations have generally argued in favour of exposure levels that cause no excess risk. In view of the important implications that flow from the choice of an acceptable risk level for a carcinogen, council wonders whether the minister should not encourage further discussion on this important issue.

As indicated in previous advisory memoranda, it is not council's role to discuss the suitability of exposure levels chosen by the government. Rather, it is council's function to comment on the analytical process employed to arrive at final standards. On the basis of council's discussions with senior ministry officials, it has been council's understanding that exposure levels for designated substances are initially set to prevent the occurrence of adverse health effects. If, after the first draft of a proposed regulation is gazetted, the ministry receives comments dealing with the social and economic impact of a proposed exposure level, the ministry will then consider the points raised, and may adjust the levels accordingly. On reviewing the ministry's background documents, however, one is left with the impression that the level of risk was set initially at a point where adverse health effects could theoretically be produced in some workers without the question of socio-economic impact having been tested. Council is, therefore, left in the position of not knowing whether industry could easily have met a lower exposure level or whether severe economic hardships would have been identified.

When government determines that a policy of acceptable risk should be adopted for a workplace carcinogen, the analytical process employed to arrive at an appropriate control level becomes complex. As the ministry has clearly indicated, there is often great difficulty in obtaining adequate epidemiological data in those cases where there has been limited public exposure to a toxic agent. Since the acceptable risk approach presupposes the need for a dose-response curve, some other method of securing the required data must be found. In the case of vinyl chloride, the ministry chose the only method available to it, and employed animal data to develop a dose-response curve for man. As the ministry's background materials emphasize, the estimate of risk obtained from such inter-species extrapolations may prove to be inaccurate. Council shares this view, and believes that the inability to state with accuracy the level of risk that humans will face at different exposure levels, on the basis of animal data, probably underscores one of the most difficult problems that government faces in the regulation of new and old carcinogens. In this climate of uncertainty, the best that can be done is to estimate risk in humans from the results of animal experiments.

In council's view, the ministry has maintained its open policy with respect to the development of designated substances regulations. In the case of vinyl chloride, however, several key analytical issues, relevant to the regulation of all carcinogens, may not have received adequate discussion. On this basis, council wonders whether consideration should not be given to holding further dialogue on the issue of acceptable risk, and on the implications that flow from this policy approach.

Footnotes

1) See generally C. Maltoni, The Value of Predictive Bioassays in Occupational and Environmental Carcinogenesis: An Example: Vinyl Chloride, in Ambio, vol. 4, no. 1, 1975.
2) International Commission on Radiological Protection, Annals of the ICRP, ICRP Publication 26, Adopted Jan. 17, 1977 (London, England: Pergamon Press, 1977). The level of acceptable risk proposed by the ICRP (i.e. 50 excess deaths per year per 100,000 workers) was considered to be the average occupational risk encountered by workers in 'safe' industries.
3) Ontario Ministry of Labour, Occupational Health and Safety Division, The Report on the Designation of Vinyl Chloride in Ontario, August 1981, pp. 5.3, G.19—G.20, G.22.
4) Preamble to the OSHA Vinyl Chloride Standard, Federal Register, Oct. 4, 1974, pp. 35890—35896.
5) International Commission on Radiological Protection, *Op.cit.*, p. 3.
6) K. E. Donnelly *et al*, Occupational Risks Within the Nuclear Power Generation Program, CNA Seminar, Nuclear Power Risks in Perspective, May 6—7, 1981, Constellation Hotel, Toronto, Ontario.
7) D. Hattis *et al*, A Case Study on the Regulation of Vinyl Chloride (Cambridge, Mass: MIT, Center for Policy Alternatives), 1976; C. Perry, 'Vinyl Chloride Protection: Less Costly than Predicted', in Monthly Labour Review, August, 1980, p. 24; and B. Whiting, Regulatory Reform and OSHA: Fads and Realities, Paper Presented to the Spring Meeting of the Industrial Relations Research Association, St. Louis, Mo., April 27, 1979.

APPENDIX 1

Agenda for Discussion

1) *The Principles Employed by the Ministry to Regulate Exposure to Vinyl Chloride and other Carcinogens*

Although the ministry does state in general terms some of the criteria that it has utilized to set levels for vinyl chloride exposure, discussion is absent on the core principles and philosophy employed by the ministry with respect to the regulation of carcinogens. For example, does the ministry accept the principle of a minimum acceptable risk or does it believe that exposure to a carcinogen should be set at the lowest achievable level? Council would appreciate some discussion on this point.

2) *The Approach Adopted by the US Occupational Safety and Health Administration (OSHA) with Respect to the Regulation of Vinyl Chloride*

The ministry's background material does not contain an analysis of the decision made by OSHA in 1974 to set an exposure limit for vinyl chloride at the 'no detectable level' (in reality, at one part per million). Council would like to know why there was no assessment in the background documents of the exposure control strategy formulated by OSHA.

3) *The Appropriateness of the 40-Hour Base for the Calculation of Time-Weighted Average Exposure Limits (TWAELs) for Vinyl Chloride*

Council would appreciate discussion on the rationale for utilizing the 40-hour base as opposed to the normal 8-hour base in the calculation of time-weighted average exposure limits for a carcinogen.

4) *The Teratogenic Effects of Vinyl Chloride*

In the background material, the ministry states that an association may exist between exposure to vinyl chloride and the incidence of congenital abnormalities in the offspring of exposed populations. Despite this possible relationship, the Code for Medical Surveillance for Vinyl Chloride, unlike the Code for Medical Surveillance of Mercury Exposed Workers, does not contain a statement to the effect that 'exposure to females of childbearing age should be kept to a minimum.' What was the ministry's rationale for treating the two substances differently?

5) *The Technological and Economic Feasibility of Achieving Lower Control Levels*

Council would like to know whether the ministry has accumulated any evidence which indicates that a one ppm TWAEL for vinyl chloride would not be technologically or economically feasible.

6) *The Meaning of the Term 'Personal Records of the Exposure of a Worker'*

A number of respondents questioned the ministry on the meaning of the term 'personal records of the exposure of a worker' contained in sub-section 7(2)(c) of the regulation. Among the points raised were the following: (1) Can the results of area monitoring be substituted for the results of personal monitoring? (2) Can the results obtained from monitoring worker (X) also be recorded for worker (Y) if both workers have the same job classification? and (3) How often should monitoring for vinyl chloride be conducted? In response to these queries, the ministry stated that 'these matters should be decided through the internal responsibility system.' Council would appreciate a discussion of the criteria employed by the ministry to determine when a matter should be clarified in a regulation and when it should be left to the internal responsibility system.

7) *The Type of Records That Must be Maintained for Workers Who Use Respiratory Equipment on A Voluntary Basis*

It is unclear from the background material whether the voluntary use of respiratory equipment by a worker must be recorded in the worker's exposure records. Council would appreciate clarification on this point.

8) *The Use of Liver Function Test Results as a Basis for Worker Removal*

Council has a concern about the use of liver function tests for the purpose of determining when a worker should be removed from a vinyl chloride worksite. Liver function tests are not specific to vinyl chloride exposure and, therefore, the risk exists that a worker could be removed from a vinyl chloride environment on the basis of an abnormal test result, notwithstanding that the abnormality did not result from exposure to vinyl chloride. Council wonders whether it would not be more appropriate to leave the decision to remove a worker exclusively to the discretion of an examining physician. Council would like to hear discussion on this point.

9) *The Appropriateness of the Procedures for Conducting and Interpreting the Results of Liver Function Tests*

Given that the ministry determines that the results of liver function tests should be used as a basis for worker removal, council would appreciate clarification on the following points:

a) In sub-section 4(1)(a) of the Code for Medical Surveillance for Vinyl Chloride, it is stated that the question of whether a particular liver function test is normal or abnormal will be judged by the laboratory performing the test on the basis of the range of test results that the laboratory normally encounters. Council wonders why the ministry has not stated the range of test results that it considers normal.

b) Sub-section 4(1)(a) also states that when a worker exhibits an abnormal liver function test result, the worker must undergo a repeat series of tests within four to six weeks. Council wonders whether this waiting period is too lengthy and notes that the preferred time period for repeat testing specified in the US Vinyl Chloride Standard is from three to four weeks.

c) Sub-section 4(1)(a) contains the further provision that a worker must be removed from exposure 'if the results of a repeat group of liver function tests show increasing abnormality of one of them or that two of them remain abnormal . . . '. Is it the ministry's position, then, that if a worker exhibits an abnormal result for liver function test (X) at point (T1) in time and, at point (T2) in time (6 weeks later), shows the same abnormal result for test (X) and, for the first time, exhibits an abnormal result for test (Y), there will be no requirement to remove the worker since two test results have not *remained* abnormal?

10) *The Return to a Vinyl Chloride Work Area*

Council notes that, unlike sub-sections 4(1)(a)(i) and (ii) of the Code for Medical Surveillance for Lead, sub-section 4(1)(a) of the Code for Medical Surveillance for Vinyl Chloride does not provide any guidance on the question of when a worker who has been removed from a vinyl chloride work area may be permitted to return to work. Council is interested in the ministry's reasons for treating the two substances differently.

11) *Fitness for Work in a Vinyl Chloride Environment*

Council also notes that sub-section 16(1) of the vinyl chloride regulation is phrased differently from sub-section 16(1) of the gazetted lead regulation. The latter provision states that 'the physician conducting the physical examination or clinical tests . . . shall advise the employer . . . and the worker whether the worker is fit *or because of a condition resulting from the inhalation, ingestion or absorption of lead* [emphasis added] is fit with limitations or unfit [to work with lead] . . .'. Sub-section 16(1) of the vinyl chloride regulation, however, omits the phrase 'or because of a condition resulting from the inhalation or absorption of vinyl chloride'. The upshot would appear to be that a worker could be declared unfit to work with vinyl chloride, notwithstanding that this unfitness did not occur as a result of exposure to vinyl chloride. Is the ministry adopting different policies for lead on the one hand and vinyl chloride on the other?

12) *An Employee's Entitlement to Workmen's Compensation Benefits*

Council's final comment deals with the issue of workmen's compensation benefits. Sub-section 16(2) of the vinyl chloride regulation states:

> 'Where a worker is removed from vinyl chloride exposure because a physical examination or clinical test discloses that the worker is unfit for work in vinyl chloride exposure and suffers a loss of earnings occasioned thereby the worker is entitled to compensation for the loss in the manner and to the extent provided by the *Workmen's Compensation Act.*'

As indicated in our comments on sub-section 16(1) of the vinyl chloride regulation, a worker could be declared unfit to work with vinyl chloride for reasons other than previous exposure to the substance (e.g. alcoholism). In this respect, one would think it highly unlikely that the Workmen's Compensation Board would award benefits for a health condition that was not occupationally induced. The concern is, therefore, that sub-section 16(2) might mislead workers. Council would appreciate discussion on this point.

APPENDIX 2

Ontario

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February 12, 1982

J. Fraser Mustard, M.D.
Chairman
Advisory Council on Occupational
Health and Occupational Safety
15th Floor
400 University Avenue
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

I attach a copy of the final vinyl chloride regulation which has been revised since the Ministry met with your task force on regulations. Changes have been made to sections 3 and 16 and the Code for Medical Surveillance. The dates on the codes have been revised.

With respect to sections 3(2) and 3(3), confusion has arisen as to the legal responsibility placed upon the employer in the work place. As these subsections are worded, responsibility for the protection of any worker, whether of the employer or of a contractor, is placed upon the employer in the work place and a contractor has no obligations to his workers under the Regulation. After considering representations that have been made, it has been deemed advisable to redraft subsection (2) to relieve the employer from responsibility towards workers of contractors who are engaged in a construction project in the work place of the employer. At the same time, it was deemed proper to maintain legal responsibility for the protection of all other workers in the work place upon the employer. To accomplish this, subsection 3(2) has been reworded as follows:

> " (2) Subject to subsection (3) an employer to whom this Regulation applies shall take every precaution reasonable in the circumstances to ensure that every worker who is not an employee

. . /2

> of the employer but is at, upon, in or near the work place of the employer and is exposed to vinyl chloride and whose health is likely to be affected thereby is protected and a worker shall comply with the requirements of the employer. "

The Ministry amended sections 16 (1) and (2) so that they are now in keeping with the wording and intent of the lead regulation. They also conform to the proposed regulation presented at the June 9, 1981 review meeting. In other words, a physician conducting the medical program for a company under the vinyl chloride control program has a duty to advise the employer whether a worker, because of a condition resulting from exposure to vinyl chloride, is fit with limitations or unfit. As you know, a worker may have health conditions arising from causes other than the work place which preclude exposure to vinyl chloride. In these circumstances, while the Ministry does not recommend the worker continue to work where he may be exposed to vinyl chloride, it believes that the decision should not be governed by the regulation when the health condition did not arise from vinyl chloride exposure at the work place.

The Code for Medical Surveillance has been revised so that it offers guidance to the physician rather than setting out specific commands. This is particularly important in the differential diagnosis of health effects that can be related to vinyl chloride exposure where there is more than one cause for the results obtained by examination and testing.

I look forward to receiving your final advice.

Yours very truly,

Robert G. Elgie, M.D.
Minister

Attach.

Ontario

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July 20, 1982

J. Fraser Mustard, M.D.
Chairman
Advisory Council on Occupational
Health and Occupational Safety
15th Floor
400 University Avenue
Toronto, Ontario

Dear Dr. Mustard:

Thank you for submitting Advisory Memorandum 82-I concerning the vinyl chloride regulation. I would like to extend my thanks to the Council members for their diligent work.

I have accepted your proposal to publish in the Ontario Gazette the codes referenced in the regulation at the same time as the regulation is published.

The Council has questioned whether the consultative process resulted in a full discussion of the risk associated with the proposed exposure limit. I have reviewed the sequence of events and have concluded that there was ample opportunity for public discussion.

As to the exposure limit, I have considered the Council's observations carefully and have concluded that the vinyl chloride regulation should include a provision requiring employers to maintain exposures at the lowest practical level below the mandated exposure limit of 2 ppm. I believe that this wording will deter the relaxation of effort in those establishments where existing exposure levels are already below the proposed maximum values.

The Council's detailed comments on a variety of analytical and legal/technical processes are dealt with in the attached memorandum prepared by the Ministry's Occupational Health and Safety Division.

I enclose for your information, copies of the revised regulation, with accompanying codes. The material will be published in the next issue of the Ontario Gazette.

Yours very truly,

R. H. Ramsay
Minister

Attach.

Ministry of Labour Comments on Advisory Memorandum 82-I

July 20, 1982

Council has set out several issues concerning the consultative, analytical, and legal/technical processes. These are addressed in order.

1. The rationale for the exposure limit and related issues

As council points out, this exposure limit was based upon a risk analysis entailing certain assumptions, which, because of the risk of cancer, were conservative. The Ministry adopted the International Commission on Radiological Protection (ICRP) criterion for determining the appropriate risk level. The logic in adopting this approach is set forth below:

> The exposure standard for radiation workers is a whole body dose of 5 rem per year. Human epidemiologicial data indicate that 1 rem whole body dose leads to an average lifetime risk of fatal malignancy of about 1 case per 10,000 workers. On the basis of these data one can infer that a risk of 5 cases per 10,000 workers per year would result if workers received a dose of 5 rem per year over their working lifetimes. The International Commission of Radiological Protection considers that large occupational groups with their recommended annual dose limit of 5 rem would experience an average lifetime risk which is comparable with that experienced in other industries considered to have high standards of safety. The same principle will hold for vinyl chloride exposure especially since most workers have exposures well below the exposure limit of 2 ppm. Consequently, the actual average risk for vinyl chloride workers will be less than that associated with the radiation limit. It should also be pointed out that this level of risk would only be attained in workers who spent all their working lives exposed to 2 ppm of vinyl chloride which is an unlikely situation.

In addition, the Council has questioned whether there has been adequate discussion of the risk level selected. Following the publication of the proposed regulation for vinyl chloride, the *Interim Report of the Designation of Vinyl Chloride in Ontario* was placed in the library of the Ministry of Labour. This document contained the rationale for the exposure limit, and in an appendix, a report prepared by the Special Studies and Services Branch dealing with the health effects of exposure to vinyl chloride; it also contained an assessment of the risk of exposed workers developing tumors. The risk of developing tumors at different levels of exposure was used to arrive at the exposure limit proposed. All the assumptions used in the risk assessment were outlined in the health effects document and were dealt with in the risk assessment itself. This document had been available to the public for eight months prior to a public meeting in June 1981. This meeting was hosted by Ministry officials to review the revisions made to the proposed regulation for vinyl chloride following the receipt of the briefs received in response to the publication of the proposed regulation in the *Ontario Gazette* in August 1980.

While the affected parties commented in their briefs on the exposure limit chosen, no comments were made on the risk assessment, the assumptions used in its development or the fact that the risk assessment forecast that exposure to 2 ppm of vinyl chloride in air would result in 5 excess tumors per 10,000 workers per year. Organized labour argued for a lower exposure level of 1 ppm because OSHA (U.S.) set the limit at a level that was as low as technologically feasible. On the other hand the vinyl chloride industry claimed that the ACGIH guideline of 5 ppm was an adequate safeguard for vinyl chloride exposure.

At a public meeting of June 9, 1981, it was explained that the exposure limit of 2 ppm of vinyl chloride in air was based on the analysis of recent scientific literature by the Special Studies and Services Branch and that the supporting documentation was available in the Ministry library for review by the public. Since no briefs had specifically mentioned the risk assessment and any discussion of this subject is of necessity extremely technical, it was not deemed necessary to discuss in detail at the public meeting the conclusions reached or the risk assessment conducted. Only those points raised in the briefs and the revisions made to the proposed regulation were brought forward. This included discussion of the time-weighted average exposure value chosen. The nature of the risk assessment was not discussed in the question period following the meeting or in the briefs received after the meeting.

The Ministry believes that there was ample opportunity for public debate of the particular model selected and used to establish the exposure limit. The opportunity was available for the parties to argue the risk assessment itself but debate was focussed, with some intensity, on the 'number' proposed.

As to the limits proposed, Council has alleged that vinyl chloride workers would be faced with an occupational risk which is 10 times that of the radiation workers. This is not a valid conclusion, since most workers exposed to vinyl chloride are exposed to levels well below the exposure limit. Consequently, the actual risk of vinyl chloride workers would be comparable to the occupational risks experienced by workers employed in industries considered to have high standards of safety.

The ICRP approach does, of course, incorporate the principle that the actual exposures experienced by workers should be kept as low as reasonably achievable. Ministry officials have discussed with Council the idea of incorporating this principle in the language of the regulation and recommended that this approach be adopted for the vinyl chloride regulation. The Ministry proposes to amend section 4. The wording proposed will deter the relaxation of effort in those establishments where existing exposure levels are already below the proposed maximum values.

2. Other issues in the analytical process

The Council raised a number of more specific issues:

- The basis of calculating a worker's exposure

- Germ cells and the Code of Medical Surveillance
- Protection of construction workers

A. *The basis of calculating a worker's exposure*

In previous discussions with Ministry officials considerable time has been devoted to the question of using 40-hour time-weighted average exposure limits rather than exposure limits based on an 8-hour period.

With respect to this question, the following reasons have been previously noted for using an exposure limit calculated over 40 hours:

- a 40-hour TWAEL gives a more appropriate indication of exposure for substances which produce chronic effects;
- the 40-hour exposure limit accords with more flexible working schedules;
- the inclusion of a ceiling limit of 10 ppm in the vinyl chloride regulation protects the worker from an excessive exposure over a short period of time.

As was noted from the calculations for various work schedules presented to Council at the meeting on vinyl chloride of November 16, 1981, the difference in exposure calculated over a 40-hour period relative to that calculated over an 8-hour period is minimal and is not significant from a health effects perspective. For those reasons, no changes in the regulation are contemplated.

B. *Germ cells and the medical surveillance code*

In the regulation respecting lead and mercury, the removal of women capable of bearing children from exposure to these substances was based upon evidence that there was risk to the developing fetus. In the case of lead, an actual level was given. In the case of mercury, definitive data are lacking but the risk was recognized by stating exposure should be kept to a minimum.

With respect to vinyl chloride, there is no definitive evidence which correlates vinyl chloride exposure with adverse reproductive outcome. The Ministry will continue to review the scientific literature on this subject and will amend the code of medical surveillance when necessary.

C. *Construction workers in vinyl chloride plants*

The Ministry's rationale for the approach taken to protect construction workers engaged on a project in an industrial establishment was explained by Dr. Elgie in his letter of February 9, 1982 responding to the Council's advice on the mercury regulation. Dr. Elgie's statement applies equally to the vinyl chloride regulation.

A separate regulation for constructors with workers exposed to vinyl chloride will provide the appropriate guidance to the construction industry to ensure that the health of workers is protected.

3. Legal/technical issues

The Ministry has the following comments on the technical issues raised in Council's memorandum.

A. *Recording voluntary use of respirators*

Council requests the Ministry to add a requirement to record the voluntary use of respirators which are not governed by the conditions set out in sections 4 and 5 of the regulation, in order to improve exposure data available for epidemiological studies. While the Ministry is sympathetic to the suggestion, a requirement to record the voluntary use of respirators, particularly when used for short periods of time, would be impractical as a general requirement for the workers and employers. The Code for Respirators which is governed by section 5 of the regulation does require the frequency of the mandatory use of respirators, to be recorded. However, where employers and workers decide to record the use of respirators worn on a voluntary basis, they may do so.

B. *Medical removal and return to work*

The Council raises the question of assistance by the medical staff of the Ministry in the situation where a disagreement exists between a physician employed by a firm and the personal physician of a worker with respect to either removal from work in a vinyl chloride exposure or subsequent return to work.

Section 16(1) places a duty on the examining physician appointed under the control program set up pursuant to section 7 of the regulation to make these decisions. Employers are also required to follow his advice. The regulation requires that the examining physician must make these decisions and advise the employer accordingly.

C. *Change in the Code for Medical Surveillance*

Council has pointed out that there is an inconsistency between the wording of subsection 4(1) of the Code for Medical Surveillance and subsection 16(1) of the regulation with respect to the requirement to report whether a worker is fit, fit with limitations or unfit for work in vinyl chloride exposure. Such a requirement is intended to be mandatory. Therefore, the phrase in the Code for Medical Surveillance in the final regulation will read as follows:

> "If the abnormality is confirmed, a decision *shall* be made by the physician as to whether the worker should be removed from vinyl chloride exposure."

Conclusion

Council argues that "several key analytical issues relevant to the regulation of all carcinogens may not have received adequate discussion" and that consideration should be given to holding further dialogue on the issue of acceptable risk.

There has been considerable controversy in all jurisdictions that have addressed the control of carcinogens in the workplace. The cancer policy developed by OSHA is still the subject of intense debate some five years after it was published and as recently as June of this year, the Administrative Conference of the United States issued a recommendation (82-5) concerning Federal Regulation of Cancer-Causing Chemicals. It remains to be seen whether the recommendations are adopted by the regulatory agencies in the United States. The use of risk assessments and the assumptions used to develop them are contentious issues even amongst the scientists who are experts in the area.

In Ontario a decision was made in the autumn of 1980 to refer this issue to the Advisory Council. The Council has established a Task Force to examine approaches to the control of carcinogens. At the same time, the Ministry proceeded to develop regulations for three carcinogens, namely vinyl chloride, coke oven emissions and asbestos, since control of these substances was a high priority. The need for a "generic" cancer policy requires further public discussion at this stage, and this is being undertaken by the Council. The Ministry will review its approach upon the receipt of the Council's report.

Advisory Memorandum 82-II

Ontario
Advisory Council on
Occupational Health &
Occupational Safety

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400 University Avenue
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June 21 , 1982.

The Honourable Russell H. Ramsay,
Minister of Labour,
400 University Avenue,
14th Floor,
Toronto, Ontario.
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Dear Mr. Minister:

On behalf of the Advisory Council, I am enclosing Advisory Memorandum 82-II in which council has reviewed the process for the development of the coke oven emissions regulation, in light of the policies and principles set out in Advisory Memorandum 78-II.

I trust that the advice provided will prove useful to you.

Yours truly,

J. F. Mustard, M.D.,
Chairman.

Enc.

cc to: T. E. Armstrong, Q.C.
Dr. A. E. Robinson

Advisory Memorandum 82-II
to the Minister of Labour
June 21, 1982

A Review by the Advisory Council of the Process Used to Develop a Standard for Coke Oven Emissions and Council's Evaluation of the Criteria Utilized to Assess the Hazard of Exposure to Coke Oven Emissions in the Workplace

INTRODUCTION

In February 1978, the advisory council and the then Minister of Labour agreed that council should be given the task of reviewing the principles and procedures used in setting occupational health standards and guidelines in Ontario. In Advisory Memorandum 78-II, council set out a list of the basic principles and procedures that should ideally characterize the policy process with respect to establishing standards, guidelines and codes. In this document, council undertook to review the criteria utilized by the Ministry of Labour to evaluate occupational health hazards and to follow the ministry's standard setting process through to its final form. It was also clearly understood that council would limit its review to the process leading to the development of ministry standards. In its memorandum, council also stated that it would require 30 days to complete its review function. In subsequent correspondence with the minister, it was agreed that, because of public interest in the area, council's review of the standard setting process should be submitted in the form of an advisory memorandum.

In February 1980, officials of the Ministry of Labour met with representatives from Algoma, Stelco and DOFASCO (the three employers within Ontario that operate coke oven batteries) and with members of the United Steelworkers of America to discuss the principal features of a proposed regulation for the control of worker exposure to coke oven emissions. Subsequent to the meeting, each of the participating organizations filed a detailed brief with the ministry. The briefs canvassed such topics as appropriate regulatory strategies for the control of coke oven emissions, and the particular elements that should be included or omitted from any proposed standard.

In June 1980, the Ministry of Labour published a Notice of Intent to designate coke oven emissions as a substance 'to which the exposure of a worker is prohibited, regulated, restricted, limited or controlled under the *Occupational Health and Safety Act*'. This was followed, in May 1981, by a notice setting forth the ministry's proposed regulation for coke oven emissions. The notice invited public comments and stipulated that such comments would be made available for public examination. At the same time, the ministry made available to interested members of the public a document entitled *Interim Report on the Designation of Coke Oven Emissions in Ontario*. The document contained a copy of the proposed regulation and three accompanying codes, along with a background discussion of several topics pertaining to the exposure of workers to coke oven emissions. On September 9, 1981, the ministry held a public meeting to discuss changes that had been made to the May 1981 version of the proposed coke oven regulation. A revised version of the regulation and accompanying codes was also distributed at this time. Invitees were told that they would have a short period of time to comment on any revisions that had been made to the regulation and codes.

On March 9, 1982, council received from the ministry a revised version of the coke oven regulation, subject to any amendments that might be made as a result of submissions made by the public after the September 9 meeting. Included with the regulation was a document entitled *The Report on the Designation of Coke Oven Emissions in Ontario*. This document contained, among other things, a summary of the views expressed by members of the public on the various provisions contained in the first and second drafts of the regulation. The type of action taken by the ministry in response to the submissions made was also outlined. The background materials supplied to council did not contain an analysis of the type of economic impact that Ontario steel producers would likely experience if the provisions contained in the proposed coke oven regulation were implemented.

After an initial review of the revised regulation and accompanying background materials, council asked that a meeting be scheduled between its Task Force on Regulations and ministry officials. The objective of this meeting was to permit task force members to explore, in greater depth, the rationale employed by the ministry to arrive at certain policy decisions. The meeting in question took place on May 13, 1982. The agenda for discussion, which was prepared for this meeting, is reproduced as an Appendix to this advisory memorandum.

During the May 13 meeting, ministry officials indicated that a number of further changes had been made to the proposed coke oven regulation and to the accompanying codes. Some of these changes arose as a result of discussions held between the ministry and council's Task Force on Regulations, while other revisions were precipitated by the ministry's dialogue with other interested groups. The ministry distributed copies of the final draft regulation and the three accompanying codes to task force members following the meeting.

As was the case in council's review of the process leading to the development of the lead, mercury and vinyl chloride regulations, council intends to focus on three aspects of the standard setting process. These are the consultative process (i.e. whether the public was provided with sufficient opportunity to comment upon and participate in the development of the regulation), the analytical process (i.e. whether the ministry assembled, reviewed and analysed the available evidence in a reasonable fashion, and whether the conclusions reached were compatible with the evidence) and the legal-technical process (i.e. whether the regulation and codes are internally consistent, and whether the intent of the ministry is expressed in a clear and unambiguous fashion).

COUNCIL'S REVIEW OF THE STANDARD SETTING PROCESS FOR COKE OVEN EMISSIONS

1. The Consultative Process

To reiterate the comments made in previous advisory memoranda, council wishes to commend the ministry for the steps it has taken to make possible public participation in the consultative process for the development of occupational health regulations. Council strongly endorses the ministry's efforts to develop an open process for the setting of standards. Council would point out, however, that the standard setting procedure employed by the ministry for the development of the proposed coke oven regulation does not conform strictly to the steps laid out by council in Advisory Memorandum 78-II. In this regard, council notes that the former Minister of Labour undertook, in his reply to Advisory Memorandum 81-I on lead, to give serious consideration to a number of suggestions made by council to enhance the quality of the consultative process.

2. The Analytical Process

In reviewing the analytical process employed to develop a standard for coke oven emissions, council's role is to judge how effectively the ministry has assembled, reviewed and analysed the available evidence. In embarking on this task, council has the advantage of examining a complex and difficult process in its final stage. Hence, council is in a position to review not only the arguments put forward by participants, but also the rationale supplied by the ministry for formulating its regulation in a particular fashion in light of the evidence and arguments raised.

As a first step in discharging its responsibilities, members of council's Task Force on Regulations met with ministry officials to seek more complete information on the rationale employed by the ministry to arrive at several important regulatory decisions. The key analytical issues taken up with ministry staff are discussed below.

(a) *The Regulatory Approach Adopted by the Ministry for the Control of Worker Exposure to Coke Oven Emissions*

During their meeting with ministry officials, task force members wished to know why different regulatory approaches had apparently been employed to set exposure levels for vinyl chloride on the one hand and for coke oven emissions on the other. Members of the task force noted that, in the case of vinyl chloride, a risk assessment approach employing animal data had been utilized, along with an estimate of acceptable risk, to establish a Time-Weighted Average Exposure Limit (TWAEL) for the substance. For coke oven emissions, on the other hand, the ministry determined that the TWAEL should be set at the lowest level that was technologically feasible.

In addressing this point, ministry officials stated that vinyl chloride and coke oven emissions are different sorts of substances. Vinyl chloride may be classified as a pure substance, while coke oven emissions represent a mixture of different types of chemicals. In the case of vinyl chloride, animal studies have been conducted, and risk models developed from the available data. For coke oven emissions, on the other hand, it has not been possible to identify with certainty the carcinogenic agent(s) present in this mixture. When one considers, as well, that the composition of coke oven emissions varies markedly according to such factors as temperature and stage of the coking process, it becomes extremely difficult to develop a suitable risk model upon which an exposure level can be set. The ministry therefore adopted a more general approach and made the decision to control coke oven emissions at the lowest level judged to be technologically feasible.

(b) *The Technological Feasibility of Achieving the 0.15 mg/m³ TWAEL for Coke Oven Emissions*

In the ministry's background documentation, there appeared to be some disagreement between the steel producers on the one hand and the ministry on the other about whether the 0.15 mg/m³ exposure level was, in fact, technologically feasible. On that basis, task force members asked the ministry to set out the evidence that had been relied upon to reach the conclusion that the 0.15 mg/m³ level could be met. In response, the ministry acknowledged that, with respect to existing batteries, it was not possible to reduce exposure levels to the 0.15 mg/m³ level exclusively through the use of engineering controls. Rather, the 0.15 mg/m³ exposure level should be viewed as a long-term target that could be achieved in new batteries, employing the most modern technology. The ministry recognized that, in the interim, exposure limits could only be complied with through the use of respiratory equipment.

According to information supplied to council from industry sources, there is no coke oven battery currently in operation where exposure to coke oven emissions has been reduced to the 0.15 mg/m³ level for all job categories. In this respect, council thinks it desirable that the ministry verify the correctness of its data base to ensure that the exposure levels that have been selected will be technologically feasible in the near future.

(c) *The Extra Health Benefits to Be Obtained from Setting the TWAEL for Coke Oven Emissions at 0.15 mg/m³*

During the meeting of May 13, 1982, task force members asked the ministry to set out its reasons for believing that a TWAEL of 0.15 mg/m³ would afford workers better health protection than a TWAEL of 0.20 mg/m³. In response, ministry officials stated that, whether one calculated lung cancer risk on the basis of a linear or quadratic dose-response model, the available data suggested that the risk would be lower at the 0.15 mg/m³ level. Furthermore, since it was apparent that neither the 0.15 nor the 0.20 mg/m³ Time-Weighted Average Exposure Limits could be achieved on a consistent basis, except through the use of respiratory equipment, a practical decision was made to minimize risk and to set the Time-Weighted Average Exposure Limit at 0.15 mg/m³. In response to a further question, the ministry indicated that a TWAEL of 0.10 mg/m³ would be impossible to achieve.

(d) *The Absence in the Proposed Regulation of a Maximum Exposure Limit (MEL)*

Members of council's Task Force on Regulations also asked ministry officials why a Maximum Exposure Limit had not been included in section 4 of the proposed coke oven regulation, when a ceiling value had been incorporated into the proposed regulation for vinyl chloride. The ministry indicated, in its response, that a MEL had not been included for two reasons:

i) It is not clear whether exposure to high concentrations of coke oven emissions over a short period of time is inherently more dangerous than long-term exposures at low concentrations.
ii) There do not exist measuring devices that will permit MELs to be calculated on an instantaneous basis. (Rather, sampling must be calculated over a prolonged period in order to collect a sufficient number of particles for counting purposes).

(e) *The Calculation of Time-Weighted Average Exposure Limits over 40-Hour Sampling Periods*

During the May 13 meeting, task force members discussed with ministry officials the appropriateness of calculating Time-Weighted Average Exposure Limits for a carcinogen over a 40-hour sampling period. In response to the point raised, ministry officials indicated that they considered coke oven emissions to represent a chronic health hazard and, on that basis, it did not matter whether TWAELs were computed over a 40 or an eight-hour period.

In Advisory Memorandum 82-I on vinyl chloride, council considered the question of whether it is desirable to calculate TWAELs for carcinogens over extended sampling periods. While some council members felt that, at low levels of exposure, it does not matter whether sampling occurs over an 8 or 40-hour period, others felt that, given i) the uncertainties inherent in the process of carcinogenesis and ii) the yet unresolved issue of whether prolonged exposures at high concentrations might be more likely to induce cell proliferation, the 8-hour sampling period would provide an extra margin of safety.

(f) *Urine Mutagenicity Testing*

During their discussions with ministry officials, task force members wondered why the ministry had referenced urine mutagenicity testing in the Code for Medical Surveillance of Workers Exposed to Coke Oven Emissions. In addressing this point, the ministry indicated that urine mutagenicity testing was made optional in the code because of the experimental nature of the procedure, and that this technique might prove useful in the future.

While council welcomes the ministry's initiative in introducing new types of biological monitoring procedures, it wishes to note that tests conducted on workers have so far indicated that exposure to coke oven emissions does not enhance urine mutagenicity.[1] Council appreciates that decisions on whether or not to offer particular biological monitoring procedures must often be based on imperfect information. In this regard, council's Task Force on Health Surveillance and Health Screening is currently preparing some general recommendations on the nature and quality of evidence required to determine whether programs of health surveillance should be launched or continued.

3. The Legal-Technical Process

As a result of discussions held between the ministry and interested groups, including council's task force, subsequent to the September 9 public meeting, several amendments have been made to the proposed coke oven regulation and to the accompanying codes. In council's view, these changes more adequately reflect the intent of the regulation. The major amendments are set out below:

i) Sub-section 8(1) of the proposed regulation now provides that an employer must adopt and implement engineering controls to reduce TWAELs to the 0.15 mg/m^3 limit or below only where it is reasonable or practical to do so. (The previous draft of the sub-section could have been interpreted to suggest that such controls must be introduced whether or not they were reasonable or practical).

ii) Section 14 of the Code for Respiratory Equipment for Coke Oven Emissions now specifies that an employer is to keep records of the frequency of use by workers of respiratory equipment. (The previous draft had only required that the fact of respirator use be documented).

iii) Sub-section 4(5) of the Code for Medical Surveillance of Workers Exposed to Coke Oven Emissions now provides that a physician must make a decision about when a worker, who has previously been removed from a coke oven worksite, may be permitted to return to work.

Council wishes to make several additional points with respect to the legal-technical process. Council believes that the following items require futher comment.

(a) *The Application of the Proposed Regulation to Employees Who Work in Coal Handling and By-Products Areas*

In the background documentation supplied to council, the ministry set out a number of reasons for its decision to exempt workers employed in coal handling and by-products areas from the ambit of the regulation. The two primary considerations upon which the ministry's decision was based were: i) Workers employed in coal handling areas are, in general, not exposed to high levels of polynuclear aromatic hydrocarbons, ii) Epidemiological studies have not demonstrated an excess risk of lung cancer among this class of workers.[2] The task force wondered, however, whether there are worksites in the jurisdiction where (either because of geographical proximity to coke ovens or due to atmospheric conditions) workers in coal handling and by-products areas might regularly be exposed to polynuclear aromatic hydrocarbons or to other carcinogens emitted by coke ovens. The task force was particularly interested in the response to this question since the ministry had indicated elsewhere in its background documentation that the coke oven regulation should not leave unprotected workers exposed to low levels of coke oven emissions.[3] In response to this concern, ministry officials indicated that the geographical layout of coking facilities in each of Ontario's steelmaking plants is different. In some worksites, coal handling, coking and by-products operations are conducted in fairly close proximity to one another. In other steel plants, however, the individual activities are more dispersed geographically. On this basis, the ministry judged that it would be impractical from an administrative point of view to have the regulation apply to work areas other than those defined in sub-section 1(c) of the proposed regulation (i.e. coke ovens, battery ends and screening stations).

Ministry officials acknowledged that, on occasion, workers in job sites downwind from coke oven batteries, could be exposed to polynuclear aromatic hydrocarbons. The implication taken from the discussion was, however, that such exposures were not of a significant nature. The ministry also pointed out that each of the steel producers in the jurisdiction has in effect an ongoing program of air monitoring and health surveillance for workers employed in coal handling and by-products activities.

While council understands the ministry's general position on this issue, it hopes that appropriate regulatory action will be taken to protect the health of workers employed in coal handling and by-products areas where an environmental hazard is found to exist.

(b) *Additional Components of a Coke Oven Emissions Control Program*

At the May 13 meeting, task force members also wished to know why the ministry had included in sub-section 7(2) of the proposed coke oven regulation (the provision dealing with the contents of coke oven emission control programs) requirements for personal protective equipment, formal training programs and adequate changing and washing facilities when similar sorts of provisions had not been specified in any of the other designated substances regulations. The ministry responded to this question in the following fashion. First, the ministry emphasized that the coke oven regulation applies to only a small number of companies (all with similar types of industrial processes) and to a limited number of job categories. In this respect, the ministry concluded that the additional provisions contained in sub-section 7(2) were capable of being implemented on a uniform basis. The ministry also expressed the general view that where a designated substance is used in a variety of industrial settings, the extra requirements set out under sub-section 7(2) could be extremely difficult to implement. A second reason for the ministry's decision to specify additional components for coke oven control programs was that both labour and management groups appeared to accept this decision.

Council appreciates that the specific components of control programs are apt to vary depending on the particular substance being regulated. It would appear, however, that the three additional provisions specified under sub-section 7(2) of the proposed coke oven regulation (particularly the requirement that a formal training program be instituted for labour and supervisory personnel on the health effects associated with workplace exposures) could equally be mandated for other designated substances control programs.[4] On a related point, council is not convinced that, simply because labour and management groups in a particular industry wish to have a provision added to (or deleted from) a regulation, government should necessarily accede to this desire.

(c) *The Inclusion of Schedule 2 in the Proposed Regulation on Coke Oven Emissions*

A further point canvassed during the May 13 meeting concerned the ministry's decision to add a second schedule (Schedule 2) to the proposed regulation on coke oven emissions. Task force members wished to know why a detailed schedule for engineering controls, work practices and hygiene facilities was included in the coke oven standard when a similar type of schedule had not been incorporated in other regulations. It was the task force's concern that the detailed requirements set out in Schedule 2 clashed with the operation and philosophy of the internal responsibility system where labour-management negotiations are relied upon to establish the specific contents of control programs. The task force also wondered whether the promulgation of detailed specification standards might inhibit technological innovation, notwithstanding the equivalency provision contained in section 18 of the proposed regulation. In response to these points, ministry officials indicated that they would have preferred to leave matters of this sort to the internal responsibility system. However, since labour wished to have Schedule 2 included, and industry did not oppose this proposal, the decision was made to add the schedule to the proposed regulation. The ministry then indicated, in reply to a question posed by the task force, that it had not determined the extent to which steel producers in the jurisdiction had already implemented the various control measures and other provisions specified in the schedule.

Council shares the view of its task force that, when specification standards are placed in regulations, they should be written in a manner that will minimize rigidity, and, thereby, encourage technological innovation.

(d) *The Provision of Respiratory Equipment to Workers in Those Situations Where Exposure Levels Are below the TWAEL*

The final point discussed in the meeting with ministry officials related to the provision of respiratory equipment to workers. Task force members wished to know why the ministry had not imposed an obligation on employers to supply respirators to workers, when requested, in those situations where exposures were below the TWAEL. In response, the ministry stated that if such a provision were placed in the regulation, an employer could argue that, by his providing respiratory equipment, the health of his workers was being adequately protected. The result would be that the implementation of engineering controls and other methods of risk reduction would be discouraged. The ministry also indicated that, at present, workers employed in the vicinity of coke ovens are already required to wear respirators.

Council is not persuaded that a provision requiring an employer to supply respiratory equipment to a worker, at the worker's request, would necessarily discourage the development of engineering controls, particularly since sub-section 17(1)(b) of the *Occupational Health and Safety Act* already imposes a duty on a worker to wear respiratory equipment when so required by an employer. Council would simply note at this stage that some members feel that since i) coke oven emissions are carcinogenic, and ii) a safe level of exposure has not been established, any worker in the vicinity of a coke oven should have the right to obtain a respirator, on request, whether exposure levels are above the TWAEL or not.

CONCLUSION

In previous advisory memoranda, council has observed that the development of occupational health regulations is a difficult and complex task, particularly in the context of an open consultative process. In the case of the proposed coke oven standard, it is clear that the dialogue conducted between the ministry and members of the public has caused important and beneficial changes to be made to the regulation and to the accompanying codes. Council is also highly appreciative of the open attitude adopted by ministry officials with respect to the points raised by its Task Force on Regulations. In council's view, the manner in which the proposed coke oven regulation has been developed testifies to the value of the consultative process as a mechanism for the formulation of more effective occupational health regulations.

Footnotes

1. M. Moller *et al*, Mutagenicity Studies with Urine Concentrates from Coke Plant Workers. In: Scandinavian Journal of Work, Environment and Health, vol.7, no.4, Dec. 1981, p.241.
2. Ontario Ministry of Labour, Occupational Health and Safety Division, The Report on the Designation of Coke Oven Emissions in Ontario, February, 1982, p.7.4.
3. *Ibid.*, p.7.18.
4. Council has commented elsewhere on the desirability of conducting health and safety training programs in the workplace. Advisory Council on Occupational Health and Occupational Safety, First Annual Report, April 1, 1978 to March 31, 1979, p.43.

APPENDIX

Agenda for Discussion

1) *The Regulatory Approach Adopted by the Ministry for the Control of Worker Exposure to Coke Oven Emissions*

   Council would like to know why the ministry has chosen to regulate coke oven emissions at the lowest level technologically feasible as opposed to adopting some other regulatory model (e.g. the risk assessment approach or ALARA).

2) *The Choice of the 0.15 mg/m³ Time-Weighted Average Exposure Limit (TWAEL) for Worker Exposure to Coke Oven Emissions*

   What are the ministry's reasons for believing that a 0.15 mg/m³ Time-Weighted Average Exposure Limit will afford workers better health protection than the higher 0.20 mg/m³ level proposed by some groups.

3) *The Technological Feasibility of Achieving the 0.15 mg/m³ Time-Weighted Average Exposure Limit (TWAEL) for Coke Oven Emissions*

   In the background materials, there appears to be some disagreement between the steel companies on the one hand and the ministry on the other with respect to whether the 0.15 mg/m³ exposure limit is, in fact, technologically feasible. On this basis, could the ministry set out for council's task force the evidence that it has relied on to reach the conclusion that the 0.15 mg/m³ level is feasible from a technological standpoint? Council would also like to know whether the ministry expects the 0.15 mg/m³ level to be met exclusively through the use of engineering controls and work practices or, as suggested at page 7.11 of the background materials, whether the continued long term use of respiratory equipment will be required to meet this objective.

4) *The Interpretation to be Placed on Sub-section 8(1) of the Proposed Regulation*

   Under sub-section 8(1) of the proposed regulation, an employer will be required 'to evaluate, adopt and implement measures and procedures by way of engineering controls as they come into existence, become available *or* [emphasis added] are reasonable or practical to reduce the exposure of a worker to below the time-weighted average exposure limit prescribed in sub-section 4(1).' One interpretation that could be placed on this sub-section is that an employer must implement engineering controls whether or not they are reasonable or practical. Does the wording contained in sub-section 8(1) accurately reflect the ministry's intention? Or must new engineering controls *also* meet the test of reasonableness or practicality?

5) *The Application of the Regulation to Employees Who Work in Coal Handling and By-Products Activities*

   At page 7.18 of the background materials, the ministry specifically rejects the concept of an action level for the implementation of a coke oven emissions control program because 'such a concept could leave unprotected workers exposed to low levels of coke oven emissions.' At page 7.4, however, the ministry makes the decision to exempt workers employed in coal handling and by-products areas from the ambit of the regulation. This decision seems to have been arrived at on the following basis: a) Workers employed in coal handling areas are, in general, not exposed to high levels of polynuclear aromatic hydrocarbons. b) Epidemiological studies do not demonstrate an excess risk of lung cancer among these workers. Council wonders, however, whether there are worksites in the jurisdiction where (either because of geographical proximity to coke ovens or because of atmospheric conditions) workers in coal handling and by-products areas are regularly exposed to polynuclear aromatic hydrocarbons or other carcinogens from coke ovens. If this is the case, then council would like to hear discussion on the question of whether it would be advisable, in these situations, to require that an initial assessment and periodic monitoring be conducted outside the immediate area of the battery, wharf and screening station.

6) *The Absence in the Proposed Regulation of a Maximum Exposure Limit (MEL)*

Council would like to know why a Maximum Exposure Limit was included in the proposed vinyl chloride regulation, but not in the proposed coke oven emissions regulation.

7) *The Calculation of Time-Weighted Average Exposure Limits over 40-Hour Sampling Periods*

Council would like the ministry to discuss with its task force the question of whether it is appropriate to calculate the 0.15 mg/m^3 TWAEL for coke oven emissions over a 40-hour sampling period when this TWAEL has been established on the basis of a quadratic dose-response model. Furthermore, is it the ministry's belief that a 0.15 mg/m^3 TWAEL, calculated over a 40-hour period, will adequately protect the health of coke oven workers in the absence of a Maximum Exposure Limit?

8) *Additional Components of a Coke Oven Emissions Control Program*

Council wishes to know why provisions for training programs, eating, changing and washing facilities, and personal protective equipment have been included in sub-section 7(2) of the proposed coke oven regulation, but not in the corresponding sections of other designated substances regulations.

9) *The Inclusion of Schedule 2 in the Proposed Coke Oven Emissions Regulation*

Council would like the ministry to clarify its reasons for including a detailed schedule for engineering controls, work practices and hygiene facilities in the Proposed Coke Oven Emissions Regulation when a similar type of schedule has not been incorporated in other regulations. Council is also interested in knowing to what extent steel companies have already incorporated the provisions contained in Schedule 2 (or their equivalents) in existing control programs.

10) *The Provision of Respiratory Equipment to Workers in Those Situations Where Exposure Levels Are Below the TWAEL*

What was the ministry's rationale for not imposing an obligation on employers to supply respirators to workers in those situations where worker exposure to coke oven emissions is below the TWAEL.

11) *The Type of Information That Must Be Included in Worker Exposure Records*

Why has the ministry concluded that information on the frequency of use of respiratory equipment need not be included in the exposure records of coke oven workers when this piece of data is required to be reported for workers exposed to either lead or mercury?

12) *The Return of an Employee to a Coke Oven Work Area*

Council notes that in the three previous regulations that it has reviewed, the appended code for medical surveillance has dealt specifically with the question of when a worker (previously removed from a worksite where a designated substance was present) might be permitted to return to work. In this respect, council wonders why a provision similar to that found in section 4 of the Code for Medical Surveillance for Vinyl Chloride was not also included in the coke oven medical surveillance code.

Ontario

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July 20,1982

J. Fraser Mustard, M.D.
Chairman
Advisory Council on Occupational
  Health and Occupational Safety
15th Floor
400 University Avenue
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

Thank you very much for Council's advice concerning the coke oven emissions regulation which is outlined in Advisory Memorandum 82-II.

I have accepted the proposal that the codes referenced in the regulation be published with the regulation in the Ontario Gazette. Enclosed for your information are copies of the regulation, with accompanying codes.

The regulation will be filed, on or about July 30th, at which time the Ministry will be informed of the date of publication in the Ontario Gazette.

I note that some of the matters raised in the memorandum have been the subject of discussion in connection with other designated substance regulations and I would refer you to our previous correspondence on those matters common to all designated substances.

I am enclosing a memorandum prepared by the Ministry's Occupational Health and Safety Division which addresses the Council's detailed comments on a variety of matters concerning the legal and technical processes adopted in developing the regulation.

Once again I wish to thank the Council members for their valued advice on this regulation.

Yours sincerely,

Russ

R.H. Ramsay,
Minister

attach.

Ministry of Labour Comments on Advisory Memorandum 82-II July 20, 1982

1. THE ANALYTICAL PROCESS

a) *The Technological Feasibility of Achieving the 0.15 mg Benzene-Soluble Fraction of Total Particulate Matter/m^3 TWAEL for Coke Oven Emissions*

Council is correct in noting that a TWAEL of 0.15 mg/m^3 cannot be achieved for all job categories on existing coke oven batteries. This level was selected with full recognition of the fact that until old batteries are rebuilt, and new batteries are constructed, respiratory equipment will be needed by workers in some job categories in order to comply with the limit as governed by Section 5 of the regulation.

Engineering controls are available to ensure that an exposure limit of 0.15 mg/m^3 can be achieved on well maintained batteries. It is recognized that there will be a continued need for the use of respiratory equipment and administrative control measures for some job classifications on existing facilities.

b) *The Calculation of Time-Weighted Average Exposure Limits Over 40-Hour Sampling Periods*

Council has noted that, as with other regulations for chronic health hazards, the time-weighted average exposure limit is calculated over a 40-hour period. The question of calculating the exposure over a 40-hour period rather than an 8-hour period has been discussed with Council with respect to the other regulations and the reasons advanced previously are valid in respect to coke oven emissions also. It is noted that Council itself was not unanimous on this topic.

c) *Urine Mutagenicity Testing*

Following the discussion with the Task Force on May 13, 1982, the section regarding urine mutagenicity testing in the Code for Medical Surveillance was removed even though it was included only as a suggestion for a physician's consideration. It is recognized that such tests are not yet a proven value as an indicator of worker exposure to coke oven emissions. With respect to the general question of health screening, the recommendations of the Council's Task Force are awaited.

2. THE LEGAL TECHNICAL PROCESS

a) *The Application of the Proposed Regulation to Employees Who Work in Coal Handling and By-Product Areas*

With regard to the application of the proposed regulation to workers in the coal handling and by-product areas, the points against such an inclusion in this regulation were discussed with Council and are as follows:

- chemical composition of the benzene-soluble fraction of the total particulate matter in samples collected from coal handling or by-product areas is different from the composition of samples of coke oven emissions.
- at the present time, epidemiological studies have not demonstrated an increased risk of lung cancer in workers in coal handling and by-product areas.

Council members may be assured that should evidence be forthcoming to indicate the need to expand coverage of the regulation, this matter will be reconsidered. In the meantime, the general provisions of the Act and regulations apply.

b) *The Inclusion of Schedule 2 in the Proposed Regulation on Coke Oven Emissions*

The Ministry's Occupational Health and Safety Division shares the view of Council that when specification standards are placed in regulations, they should minimize rigid engineering approaches and thereby encourage technological innovation. It is considered that Schedule 2 read in conjunction with Section 8(1) in fact meets these objectives. Section 8(1) requires companies to review emerging technology and to determine whether it is practical and reasonable to adopt new measures to reduce emission levels. The provisions in Schedule 2 attached to the coke oven emissions regulation were requested by labour representatives to provide some degree of uniformity in the control of emissions for specified job sites. With minor modification the provisions requested were considered both practical and flexible.

c) *The Provision of Respiratory Equipment to Workers in Those Situations Where Exposure Levels are Below the TWAEL*

The provision of respirators to workers on request has received considerable discussion during the development of the designated substances regulations. Consideration was given to requiring employers to provide workers with respirators at the request of workers. The Ministry believes that such a provision might discourage the introduction of engineering controls. The Ministry would not want to include a requirement in the regulation which could deter employers from meeting their primary obligation with respect to engineering controls. It is understood that workers on the coke ovens are provided with respirators by their employers at the present time. It is not being brought to the attention of Ministry inspectors that workers who have requested respirators have not been provided with them. Should contrary evidence be forthcoming, this matter will be reconsidered.

Advisory Memorandum 82-III

Ontario

Advisory Council on
Occupational Health &
Occupational Safety

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416/965-2448

July 12, 1982

The Honourable Russell H. Ramsay,
Minister of Labour,
400 University Avenue,
14th Floor,
TORONTO, Ontario.
M7A 1T7

Dear Mr. Minister:

On behalf of the Advisory Council, I am pleased to submit Advisory Memorandum 82-III, in which council has reviewed the process for the development of the interim asbestos regulation in light of the policies and principles enunciated in Advisory Memorandum 78-II.

As you are aware, the chairman of the Advisory Council sits as a commissioner on the Royal Commission on Asbestos. Since the commission will shortly be providing advice to the government on matters relating to asbestos exposures, the chairman thought it appropriate that he refrain from participating in the development of the formal advice contained in this document.

In view of the fact that many of the issues addressed in council's advisory memorandum are likely to be discussed by the Royal Commission, you might wish to consider the option of providing a copy of this document, and your reply thereto, to the commission for its consideration.

Council is pleased to have participated in the process by which an interim asbestos regulation was developed.

Yours truly,

A. D. Wolfson
Vice-Chairman.

Encl.

cc to: Mr. T. E. Armstrong, Q.C.
Dr. A. E. Robinson

Advisory Memorandum 82-III
to the Minister of Labour
July 12, 1982

A Review by the Advisory Council of the Process Used to Develop an Interim Standard for Asbestos and Council's Evaluation of the Criteria Utilized to Assess the Hazard of Asbestos Exposure in the Workplace

INTRODUCTION

In February 1978, the advisory council and the then Minister of Labour agreed that council should be given the task of reviewing the principles and procedures used in setting occupational health standards and guidelines in Ontario. In Advisory Memorandum 78-II, council set out a list of the basic principles and procedures that should ideally characterize the policy process with respect to establishing standards, guidelines and codes. In this document, council undertook to review the criteria utilized by the Ministry of Labour to evaluate occupational health hazards and to follow the ministry's standard setting process through to its final form. It was also clearly understood that council would limit its review to the process leading to the development of ministry standards. In its memorandum, council also stated that it would require 30 days to complete its review function. In subsequent correspondence with the minister, it was agreed that, because of public interest in the area, council's review of the standard setting process should be submitted in the form of an advisory memorandum.

In June 1980, the Ministry of Labour published a Notice of Intent to designate asbestos as a substance 'to which the exposure of a worker is prohibited, regulated, restricted, limited or controlled under the *Occupational Health and Safety Act.*' This was followed, in August 1980, by a notice setting forth the ministry's proposed regulation for asbestos. The notice invited public comments and stipulated that such comments would be made available for public examination. At the same time, the ministry distributed copies of the proposed regulation and two accompanying codes to interested members of the public. In October 1980, the ministry distributed a document entitled *Interim Report on the Designation of Asbestos in Ontario.* This document dealt with such topics as the use of asbestos in Ontario, workplace exposures to asbestos, the control of such exposures and the health effects of asbestos. Each interim report also contained a copy of the proposed regulation and codes. On September 22, 1981, the ministry held a public meeting to discuss changes that had been made to the August 1980 version of the regulation. A revised version of the proposed regulation and accompanying codes was distributed at this time, along with an entirely new Code for Medical Surveillance of Asbestos Exposed Workers. Invitees were told that they would have a short period of time to comment on any revisions that had been made to the regulation and codes.

On April 1, 1982, the Minister of Labour transmitted to council a revised version of the asbestos regulation, subject to any additional amendments that might be made as a result of submissions received after the September 22 meeting. Included with the regulation was a document entitled *The Report on the Designation of Asbestos in Ontario.* This document contained, among other things, a summary of the views expressed by members of the public on the various provisions contained in the first and second drafts of the regulation. The type of action taken by the ministry in response to the submissions made was also outlined. The background materials supplied to council did not contain an analysis of the type of economic impact that Ontario industry would likely experience if the provisions contained in the proposed asbestos regulation were implemented. The covering letter which accompanied the proposed regulation is attached as Appendix I.

After an initial review of the revised regulation and accompanying background materials, council asked that a meeting be scheduled between its Task Force on Regulations and ministry officials. The objective of this meeting was to permit task force members to explore, in greater depth, the rationale employed by the ministry to arrive at certain policy decisions. The meeting in question took place on June 4, 1982. The agenda for discussion, which was prepared for this meeting, is reproduced in Appendix II of this advisory memorandum.

As was the case in council's review of the process leading to the development of other designated substances regulations, council intends to focus on three aspects of the standard setting process. These are the consultative process (i.e. whether the public was provided with sufficient opportunity to comment upon and participate in the development of the regulation), the analytical process (i.e. whether the ministry assembled, reviewed and analysed the available evidence in a reasonable fashion, and whether the conclusions reached were compatible with the evidence) and the legal-technical process (i.e. whether the regulation and codes are internally consistent, and whether the intent of the ministry is expressed in a clear and unambiguous fashion).

COUNCIL'S REVIEW OF THE STANDARD SETTING PROCESS FOR ASBESTOS

1. The Consultative Process

To reiterate the comments made in previous advisory memoranda, council wishes to commend the ministry for the steps it has taken to make possible public participation in the consultative process for the development of occupational health regulations. Council strongly endorses the ministry's efforts to develop an open process for the setting of standards. Council is also cognizant of the special circumstances that surrounded the publication of the first seven designated substances regulations and the difficulty of adhering strictly to the procedures set out by council in Advisory Memorandum 78-II. In this regard, council notes that the former Minister of Labour undertook, in his reply to Advisory Memorandum 81-I on lead, to give serious consideration to a number of suggestions made by council to enhance the quality of the consultative process.

One of the points raised by council in previous advisory memoranda concerned the ministry's decision not to gazette the codes that are appended to designated substances regulations. Council has suggested that the failure to bring the codes to the public's attention at an early stage in the standard setting process may cause these documents to receive less than adequate scrutiny. Considering that the codes have been incorporated into the designated substances regulations and, therefore, have legal status, council believes that these documents should be distributed with the first draft of each regulation in order to maximize public input. Council understands that the ministry is considering this issue and will make its position known shortly.

2. The Analytical Process

In reviewing the analytical process used to develop a standard for asbestos, council's role is to judge how effectively the ministry has assembled, reviewed and analysed the available evidence. In embarking on this task, council has the advantage of examining a complex and difficult process in its final stage. Hence, council is in a position to review not only the arguments put forward by participants, but also the rationale supplied by the ministry for formulating its regulation in a particular fashion in light of the evidence and arguments raised.

As a first step in discharging its responsibilities, members of council's Task Force on Regulations met with ministry officials to seek more complete information on the rationale employed by the ministry to arrive at several important regulatory decisions. The key analytical issues taken up with ministry staff are discussed below.

a) *The Rationale for the Choice of the Time-Weighted Average Exposure Limits (TWAELs) Contained in the Proposed Interim Asbestos Regulation*

During the meeting of June 4, 1982, task force members wished to know why the ministry had established different TWAELs for chrysotile, amosite and crocidolite (1.0, 0.5 and 0.2 f/cm^3 respectively), when Dr. Finkelstein, the scientist responsible for preparing the ministry's health effects study, had recommended that a TWAEL of 0.5 f/cm^3 be set for all forms of asbestos.[1] In response to this question, ministry officials stated that the control levels which had been selected were based on the recommendations of the British Advisory Committee on Asbestos (BACOA).[2] It was the ministry's view that the BACOA report provided the best source of current information on the selection of appropriate exposure limits for asbestos. Ministry officials then indicated that the recommendations contained in Dr. Finkelstein's report were not adopted for the following reasons:i) Recent epidemiological studies conducted by Dr. Finkelstein (upon which the recommendations were founded) have not been subjected to extensive peer review. ii) The Royal Commission on Asbestos has not tendered its advice on the question of control limits for asbestos. iii) The ministry wished to provide asbestos workers with a further measure of health protection as expeditiously as possible.

In its discussions with task force members, the ministry emphasized that the exposure levels set out in the proposed asbestos regulation should be regarded as interim standards only. It is the ministry's intention to review all facets of the regulation, including the choice of control levels, when the Royal Commission on Asbestos submits its final report to the provincial government. The ministry indicated, furthermore, that, should any amendments be made to the asbestos regulation, in light of the recommendations of the royal commission, these will be distributed to the public for comment. In addition, the advisory council will be given the opportunity to review the process by which the final regulation is developed.

While council members have divergent views concerning i) the exposure levels specified in the interim regulation, and ii) the ministry's decision to set different control limits for different types of asbestos, council understands the ministry's desire to promulgate an asbestos standard in an expeditious manner.

b) *The Rationale for the Choice of the Maximum Exposure Limits (MELs) Contained in the Proposed Interim Asbestos Regulation*

At the June 4 meeting, task force members wished to know why the decision had been made to i) increase the MEL for amosite from 2.0 f/cm^3 to 2.5 f/cm^3, and ii) reduce the MEL for crocidolite from 2.0 f/cm^3 to 1.0 f/cm^3. In response to these questions, the ministry indicated that the amendments were made to ensure that, for each of the asbestos types being regulated, the Maximum Exposure Limit exceeded the Time-Weighted Average Exposure Limit by a multiple of five. The ministry stated, furthermore, that the general practice of establishing MELs that are from two to five times higher than TWAELs was adopted by the American College of Governmental Industrial Hygienists (ACGIH), and that the ministry has simply followed this practice.

Council wishes to draw to the ministry's attention the fact that the ACGIH has dropped from its TLV publication the appendix which had, in the past, set out a range of multiples to be utilized in the calculation of Maximum Exposure Limits.[3] Furthermore, it is council's understanding that, even when Appendix D was an integral part of the ACGIH document, the maximum multiple specified for the establishment of MELs was three, rather than five.[4]

c) *The Model Employed for the Regulation of Asbestos and Other Workplace Carcinogens*

In the background materials provided to council, the statement is made that an exposure standard of one to two fibres per cubic centimetre '*might* produce an excess cancer risk of one to two per cent which [is] comparable to the risk posed to radiation workers by the current occupational standards for radiation exposure.'[5] In view of this statement, task force members asked the ministry whether an acceptable risk approach was being employed to set exposure limits for asbestos. In response to this question, ministry officials emphasized that no judgment had been made about the acceptability of a possible one to two per cent excess cancer risk. The ministry reiterated that the TWAELs set out in the proposed regulation were based on the recommendations of the British Advisory Committee on Asbestos. Ministry officials added that, although the exposure levels chosen could theoretically produce an excess cancer risk of one to two per cent, the levels were not selected for this reason. Task force members then wished to know whether the ministry considered that a potential one to two per cent excess cancer risk was reasonable. Ministry officials responded by stating that it is up to the public and the politicians to judge whether a particular level of risk is acceptable. It is the ministry's function to provide advice to government based on the best available information. On the basis of the evidence at hand, the ministry concluded that the exposure levels put forward in the regulation were reasonable. The ministry added that it had not received any comments from the public on the broad topic of risk assessment.

From the response provided, it would appear that the ministry has chosen not to advance a general model for the regulation of all workplace carcinogens. Rather, the ministry has decided to treat individual substances on a case by case basis. With respect to asbestos, the ministry has selected a regulatory approach which, at least implicitly, accedes to the notion of a minimum acceptable risk.

In Advisory Memorandum 82-I, council reviewed the process employed by the ministry to develop a regulation for vinyl chloride, which is also a known carcinogen. In this document, council observed that the analytical process followed by the ministry to set exposure levels for the substance (which included the application of an acceptable risk principle) had not been adequately debated by the public. Council then suggested that the minister give consideration to holding further discussion on the issue of acceptable risk. In council's opinion, the same sort of public dialogue could serve a useful purpose in the case of the asbestos regulation, where input from interested parties did not focus on this regulatory issue. In view of the ministry's desire to promulgate an interim asbestos standard in an expeditious fashion, it might be appropriate that the proposed discussions take place before a final asbestos regulation is enacted, in light of the recommendations put forward by the royal commission.

d) *The Requirement that All Exposures to Asbestos Be Kept as Low as Reasonably Achievable (The ALARA Principle)*

During their meeting with ministry officials, task force members wished to know why a requirement had not been placed in the proposed regulation to the effect that all exposures to asbestos must be kept as low as reasonably achievable. In response to this question, the ministry stated that, while the ALARA approach had been considered, the decision was made not to adopt this philosophy at the present time. The task force also gathered from the general context of the discussion that the ministry was awaiting the advice of the royal commission on this matter.

Council would note that the British Advisory Committee on Asbestos (whose recommendations on exposure limits have generally been accepted by the ministry) has recommended that a legislative provision be enacted requiring that all exposure to asbestos dust be reduced to the minimum level that is reasonably practical.[6] In this respect, some members of council feel that the ministry has been unduly selective in its adoption of the British advisory committee's recommendations.

e) *Alternative Policy Approaches for the Control of Asbestos Exposures*

At the June 4 meeting, task force members asked the ministry to elaborate on its reasons for not including in the proposed regulation i) a statutory ban on the use of crocidolite, ii) a statutory ban on the non-essential uses of other forms of asbestos, and iii) a provision requiring that asbestos substitutes be employed in the jurisdiction, wherever feasible. In response to the first point, ministry officials stated that, by setting a TWAEL of 0.2 f/cm^3 for crocidolite, one would virtually eliminate the use of this fibre type. The ministry also indicated that there is probably very little crocidolite currently being utilized in Ontario worksites. In addressing council's second question, the ministry stated that, even if one adopted a policy of prohibiting the non-essential use of asbestos, one would still have to deal with sources of asbestos already in the workplace. On the issue of substitution, ministry officials pointed out that an inter-ministerial committee is presently examining the question of whether there exist suitable asbestos substitutes. The committee, it was noted, is paying special attention to the health hazards that could be associated with replacement materials. Task force members gathered from the discussion that, once the inter-ministerial committee reports, the ministry may re-examine the question of whether a substitution requirement should be placed in the regulation.

Council has a number of comments to make with respect to the explanations provided by the ministry. On the issue of control strategies for crocidolite, council wonders why the ministry has not followed the advice of the British advisory committee and at least banned the import of this fibre type into the jurisdiction. With respect to the use of other forms of asbestos, council appreciates that the introduction of market controls will not affect those sources of asbestos already present in the workplace. A statutory provision prohibiting the future use of asbestos for non-essential purposes could, however, reduce the total amount of asbestos exposure in Ontario worksites. On the related issue of substitution, council understands the ministry's desire to await the advice of the inter-ministerial commmittee and the royal commission on this policy alternative. Council hopes that the studies being conducted will endorse the principle of substitution and provide information on materials available to replace asbestos.

f) *The Exposure Levels for Asbestos Currently Being Achieved in Ontario Worksites*

Prior to their meeting with ministry officials, task force members asked to be provided with statistics on i) the percentage of worksites within the province that are achieving control levels below 1.0 f/cm^3, and ii) the percentage of asbestos workers who are exposed to Time-Weighted Average Exposure Limits below 1.0 f/cm^3. During the June 4 meeting, the ministry shared with the task force data obtained from air quality assessments that had been conducted in 115 worksites over the last two years. The data collected revealed the following information:

i) Sixty per cent of the worksites tested recorded maximum exposure readings below 1.0 f/cm^3. (A higher proportion of workplaces would, therefore, have been able to achieve Time-Weighted Average Exposure Limits of 1.0 f/cm³).

ii) Seventy-one per cent of all workers sampled were exposed to maximum fibre concentrations below 1.0 f/cm³. (An even higher proportion of workers would, thus, have been exposed to TWAELs below 1.0 f/cm³).

The ministry acknowledged that the statistics presented were not the product of a comprehensive scientific study, but simply the aggregate results obtained from routine airborne monitoring of Ontario worksites. Ministry officials indicated further that manufacturing, construction and some office establishments were included in the sample, and that several workplaces may have been tested up to three or four times. It was the ministry's view that the majority of the worksites monitored probably had some asbestos in use. The ministry also stated that it had evaluated data obtained from air quality assessments conducted on 90 firms that either manufacture or use products containing asbestos. On the basis of this data source, the ministry concluded that firms of all types are able to achieve the 1.0 f/cm³ exposure level, on a time-weighted average basis, and that many firms are controlling exposures at the 0.5 f/cm³ level (although the precise figures are not known). The ministry also indicated that the levels recorded for some firms were higher than 5.0 f/cm³.

In council's view, the data collected by the ministry is not of a sufficient quality to permit one to calculate accurately the percentage of firms that are able to achieve TWAELs of 1.0 f/cm³ or 0.5 f/cm³ on a consistent basis. In order for this information to be provided, a comprehensive survey of the airborne exposure levels recorded in all plants that either use or manufacture asbestos products would have to be undertaken. The sampling techniques employed in such a survey would have to be structured to take into account the day-to-day variations in fibre levels. In Advisory Memorandum 81-I on lead, council has suggested that information of this sort should be made available to the public at an early stage in the standard setting process.[7]

g) *The Costs to Industry of Meeting Interim Exposure Limits*

During the June 4 meeting, task force members asked ministry officials to comment upon the excess costs that might be imposed on industry by the policy of promulgating an interim exposure limit and, shortly thereafter, possibly establishing a different exposure level based on the advice of the royal commission. In addressing this point, ministry officials indicated that they did not have any concrete data to suggest whether extra costs would be incurred by the approach taken. The ministry noted, however, that the royal commission is conducting a detailed study of the costs that different asbestos-related industries will be required to incur in order to meet various exposure levels. In a more general context, the ministry indicated that, for future designated substances regulations, it might consider the option of compiling data on the ability of firms to meet different exposure limits. This matter, the ministry suggested, should be discussed in greater detail with the advisory council.

3. The Legal-Technical Process

At the June 4 meeting, task force members also raised a number of points relating to the legal-technical aspect of the standard setting process. The key issues discussed with ministry officials are set out below.

a) *The Definition of the Term 'Asbestos Fibre'*

Sub-section 1(b) of the proposed asbestos regulation defines an asbestos fibre as one 'with a length more than five micrometres and a width less than three micrometres and a length to width ratio not less than three to one as viewed in a phase contrast optical microscope at 400 to 500 magnification.' Task force members asked the ministry to elaborate upon the reasons for the choice of this definition, particularly since the US Asbestos Standard defines the term 'asbestos fibre' in a different fashion.[8] In response, the ministry stated that the definition contained in the proposed regulation was selected for the following reasons:

i) The definition facilitates the counting of fibres by phase contrast microscopy.
ii) The definition has been widely accepted in other jurisdictions.

Ministry officials acknowledged that the definition selected was arbitrary and, to some degree, based on historical practice. It was further conceded that, simply because a fibre falls outside the prescribed definition, it does not necessarily follow that the asbestos in question is to be regarded as harmless. Rather, the hope is that by controlling the range of fibre sizes detectable by phase contrast microscopy, one will also be controlling smaller fibres, which could potentially pose a health risk.

In council's view, the definition of asbestos fibre contained in the proposed regulation depends for its validity on the assumption that there is a more or less similar distribution of fibre sizes to be found in different asbestos worksites. Council understands that there are studies being conducted in the area. When the results of this research are forthcoming, regulators will be in a better position to determine whether asbestos fibres need to be counted on a different basis. On the question of which counting technique should be employed in the interim, some council members believe that phase contrast microscopy is the only counting method available that is both practical and readily accessible. Other members take the view, however, that electron microscopy should be established as the preferred counting technique, since no other type of microscopy is able to detect the presence of very short and potentially harmful asbestos fibres.

b) *Asbestos Exposures in Education Institutions*

In their discussions with ministry officials, task force members asked the ministry to elaborate on its reasons for not making the proposed asbestos regulation apply to teachers and to academic staff employed in educational institutions. In response, the ministry indicated that a regulation will shortly be promulgated to bring teachers under the ambit of the *Occupational Health and Safety Act.* When this regulation is enacted, the asbestos regulation, in its final form, will apply to teachers covered under the *Education Act*.[9] The task force was also told that a similar type of regulatory strategy would soon be developed for academic staff employed by universities and related institutions.

c) *Asbestos Exposures in Office Worksites and the Role of Joint Health and Safety Committees*

During the meeting of June 4, task force members noted that section 8 of the *Occupational Health and Safety Act* does not provide clear guidance on the question of whether a joint health and safety committee must be established in an office worksite when an assessment, conducted pursuant to section 6 of the proposed asbestos regulation, discloses that a worker is likely to inhale or ingest asbestos and that the health of the worker may be affected thereby. Members observed that, under sub-section 8(1) of the Act, an employer is not required to establish a joint health and safety committee in worksites used for office purposes. By virtue of sub-section 8(2), however, a committee must be set up in a workplace in respect of which a designated substances regulation applies. Members noted, as well, that neither of the sub-sections is made subject to the other. Rather, both sub-sections 8(1) and 8(2) are made subject to sub-section 8(3). The latter sub-section permits the minister to order that a joint health and safety committee be established, notwithstanding what is stated elsewhere in section 8. The task force reasoned, therefore, that it was within the minister's discretion to order that a joint health and safety committee be established in an office workplace where asbestos is present. On the assumption that the task force's interpretation of section 8 was correct, ministry officials were asked what criteria would be employed to determine whether a committee should be set up in these circumstances. In response to this question, ministry officials indicated that, pursuant to sub-section 8(4) of the Act, the minister is not permitted to order that a committee be established in a workplace unless a request to this effect had been received from either labour or management representatives. Once such a request is submitted, the minister will consider each case on its own merits, taking into account the additional factors specified under subsection 8(4).

Council wishes to make several comments which relate to the ministry's response. First, council believes that the ministry may be interpreting sub-section 8(4) of the Act in too rigid a fashion. While the ministry's position is that a request from either labour or management is a condition precedent to an order being made under sub-section 8(3), it could equally be argued, on a fair reading of sub-section 8(4), that a request is merely one of a series of factors that the minister must consider. Whichever interpretation is thought to be correct, however, council believes that the minister should have a residual discretion to order that a joint health and safety committee be constituted, where necessary, irrespective of whether a specific request has been received. Council also wishes to emphasize that the presence of a joint health and safety committee (or like body) is central to the effective implementation of all designated substances regulations, whatever the category of workplace involved. In this respect, council suggests that the minister conduct a review of the provisions contained in section 8 of the Act to ensure that they do not conflict with the basic philosophy of the designated substances regulations.

d) *Asbestos Control Programs*

Pursuant to sub-section 7(1) of the proposed asbestos regulation, an employer must institute an asbestos control program when a workplace assessment discloses i) that a worker is likely to inhale or ingest asbestos, and ii) that the health of the worker may be affected thereby. Task force members wished to know whether it was the ministry's intention to issue more detailed guidelines to help labour and management representatives determine when a control program should be established. In response to this question, ministry officials indicated that the regulation did not specify an action level for the introduction of a control program since workers may have varying susceptibilities to designated substances. Instead, the ministry had left it up to the parties in the workplace to iron out the precise details of individual control programs, taking into account such factors as the nature and extent of exposures typically encountered at a job site. The ministry agreed, however, that, in the case of asbestos, difficulties could arise in determining whether exposure to the fibre was likely to affect a worker's health. In this respect, ministry officials informed the task force that explanatory materials would be developed to provide guidance on the subject of when a control program should be put into place.

Council shares the ministry's view that guidelines relating to the introduction and scope of asbestos control programs should be promulgated. Council believes that the guidelines which are developed should indicate generally the levels of exposure that are felt to be safe and the categories of workers who should undergo health surveillance. In council's view, such guidelines would be especially useful in small workplaces, where the internal responsibility system may not have the expertise to determine which class of workers should be considered at risk. Council would also point out that (smoking histories aside) it is not aware of any medical evidence which suggests that individual workers have different susceptibilities to asbestos.

e) *Training Programs for Supervisors and Workers Employed in Asbestos Job Sites*

During the June 4 meeting, task force members asked the ministry why sub-section 7(2) of the proposed asbestos regulation did not require that an asbestos control program include a formal training program for supervisors and workers on the health effects of asbestos, and on measures for the control of asbestos exposures, when an analogous sort of provision had been incorporated into sub-section 7(2)(f) of the proposed coke oven regulation. In addressing this point, the ministry indicated that formal training programs were mandated under the coke oven regulation for two reasons: i) A provision of this nature was sought by both labour and management groups. ii) The coke oven regulation applies to only a small number of companies, all with similar types of industrial processes. The ministry also pointed out that, under sub-section 14(2)(a) of the *Occupational Health and Safety Act*, an employer is already required to provide information and instruction to a worker to protect the worker's health and safety.

In Advisory Memorandum 78-III, council emphasized the importance of health and safety training programs conducted in the workplace.[10] While council appreciates that sub-section 14(2)(a) of the Act imposes a general obligation on employers to provide instruction to workers, it simply wishes to note that the wording contained in sub-section 7(2)(f) of the proposed coke oven regulation sets out the required parameters of a training program in greater detail.

f) *The Doctor-Patient Relationship in the Context of Government Mandated Health Surveillance Programs*

During the June 4 meeting, task force members sought the ministry's view on the question of whether a doctor-patient relationship comes into being when a physician tests or examines a worker, pursuant to the provisions of the *Occupational Health and Safety Act* and regulations. In addressing this issue, ministry officials indicated that, in their view, the physician in industry enjoys a doctor-patient relationship with any worker who is examined. Council understands from this reply that the examining physician must i) observe the requirements of medical confidentiality, and ii) disclose to a worker any evidence of an adverse health condition.

g) *Access by Researchers to Exposure Records that Are Made Part of a Worker's Medical Record*

During their meeting with ministry officials, task force members asked whether exposure records, which by virtue of sub-section 14(2) of the proposed asbestos regulation, are made part of a worker's medical record, will be accessible to accredited researchers or whether the requirements of medical confidentiality will apply. In response to the question posed, ministry officials indicated that since exposure records are not considered confidential in their original format, they should not obtain this characteristic simply because of their incorporation into a medical record. The ministry also took the view that exposure records should be made available to accredited researchers.

h) *Asbestos Registers*

A related issue canvassed during the June 4 meeting concerned the desirability of establishing a central register which would list the names of workers in the jurisdiction who had been occupationally exposed to asbestos. In discussing this point, the ministry indicated that sub-section 14(1) of the proposed asbestos regulation will require that exposure records be kept for asbestos workers. Thus, the basic elements of an asbestos register will soon be in place. Ministry officials also pointed out that construction employers are now required to supply to the ministry the names of all employees who have worked on asbestos removal projects or who have otherwise come into contact with asbestos. The ministry further suggested that the general issue of whether a central register should be established for workers who have been occupationally exposed to any class of carcinogen could be a matter for future discussion with the advisory council.

In council's view, the establishment of a central register could assist greatly in determining whether a worker suffering from an asbestos-related disease had, in fact, been occupationally exposed to asbestos. Workmen's compensation decisions could thus be made simpler and more equitable. Council has also indicated in Advisory Memorandum 80-IV that the value of registers could be enhanced for epidemiological purposes if data on worker exposures were included in these records.[11] Council looks forward to discussing with ministry officials the various strategies that could be employed to develop registers for carcinogens and other toxic agents.

i) *The Medical Removal of an Employee from an Asbestos Work Area*

Pursuant to sub-section 4(3) of the Code for Medical Surveillance of Asbestos Exposed Workers, three steps must be taken before a worker can be removed from an asbestos exposure environment:

i) The plant physician must inform the Workmen's Compensation Board (WCB) and the Occupational Chest Disease Service (OCDS) that the worker has signs of asbestos induced disease.
ii) The WCB and OCDS must provide the plant physician with a diagnostic opinion.
iii) If the presence of asbestos induced disease is confirmed, the plant physician must then determine whether the worker is fit, fit with limitations or unfit for continued exposure to asbestos.

Considering that the diagnosis of asbestos induced disease is a complex matter, and that there is uncertainty with respect to whether an employee with a slight degree of pulmonary impairment should be removed from an asbestos worksite, the task force asked ministry officials why guidelines had not been prescribed to help physicians determine whether a worker is suffering from an asbestos induced disease, and whether further exposure to asbestos could cause a worker's health to deteriorate. In responding to this concern, the ministry emphasized that the diagnostic procedures set out in the Code for Medical Surveillance of Asbestos Exposed Workers (i.e. chest X-rays and pulmonary function tests) will be conducted in accredited facilities. Furthermore, the ministry felt confident that the plant physicians who would initially interpret X-rays and pulmonary function tests were sufficiently competent to detect signs of asbestos induced disease. The ministry also stressed that the WCB-OCDS panel which would provide further diagnostic advice to plant physicians was composed of experts in the field of occupational chest diseases. For these reasons the ministry felt that adequate safeguards were in place to ensure that correct diagnoses would be made. In pursuing the points raised, task force members emphasized that there is wide disagreement, even among experts, on the question of what signs constitute an early indication of asbestos induced disease. On that basis, members thought it essential that a set of criteria be issued to ensure that different physicians will interpret the results of clinical tests in a consistent fashion. In this respect, it was pointed out that the International Labour Organization (ILO) has developed a systematic method for the classification of radiographic changes in the chest caused by the inhalation of mineral dusts,[12] and that this approach has gained widespread approval in the scientific community.[13] Task force members also noted that similar types of guidelines had been formulated to assist in the interpretation of pulmonary function tests.[14] Task force members felt that, in the absence of guidelines for the interpretation of clinical tests, there could be no guarantee that diagnostic criteria would be applied in a uniform and equitable fashion across the province.

On the issue of worker removal, task force members observed that, although clinical tests may help to detect the presence of asbestos related disease, they are seldom useful in determining whether an employee with asbestosis can continue to work in an asbestos environment. Although it is generally agreed that, among workers with severe cases of asbestosis, the disease will progress irrespective of subsequent exposures, the evidence suggests that, with respect to workers with the earliest signs of asbestosis, progression may not be inevitable.[15] Should a worker with early indications of this disease continue to be exposed to asbestos, however, the degree of fibrosis could evolve to a point where the disease process might become progressive. On the basis that an asbestotic condition might warrant removal in one case (where the disease had not yet become progressive) but not in another (where the disease would inevitably progress irrespective of subsequent exposures), task force members wished to know why the ministry had not set out any guidelines on the difficult question of when an employee should be removed from an asbestos job site. Criteria of this type, it was felt, would be particularly helpful since it is the plant physician, rather than the WCB, who is ultimately responsible for determining whether a worker is 'fit, fit with limitations or unfit [to be exposed to asbestos].' In response to this suggestion, a representative from the Workmen's Compensation Board who was present at the meeting stated that it is almost impossible to lay out two or three criteria and to say that if these are met an employee should be removed from an asbestos worksite. Rather, each case must be judged on its own merits, taking into account a series of factors that are judged to be relevant. At the end of the discussion, both ministry officials and task force members agreed that guidelines pertaining to the diagnosis of asbestos induced disease and the question of worker removal should be promulgated. It was further acknowledged that such guidelines should be placed in the explanatory materials that will accompany the interim asbestos regulation.

In council's view, a regulatory scheme for the removal of workers whose health may be affected by continued exposure to a designated substance must satisfactorily address two important and inter-related issues. First, criteria must be specified to help physicians determine when a worker is suffering from a job-related disease and when further exposure to a toxic agent is likely to cause a deterioration of the worker's health. Second, clear policy guidelines must be set out to indicate under what circumstances a worker who is removed from a job site as a result of exposure to a designated substance is entitled to workmen's compensation benefits, including the right to be re-trained. It would appear that neither of these issues has received adequate treatment in the Code for Medical Surveillance of Asbestos Exposed Workers.

Council agrees with its task force that criteria for the diagnosis of asbestos induced disease and for worker removal should be promulgated. Since it is crucial that all parties in the system have maximum confidence that decisions on impairment, fitness for work and disability are based on uniform and scientifically valid criteria, council believes that the guidelines developed, insofar as they affect plant physicians, should be legally binding. In this respect, the guidelines should be included in the Code for Medical Surveillance of Asbestos-Exposed Workers. In the case of diagnostic criteria, the provisions sought could resemble those contained in the *Standard for Determining Total Disability or Death Due to Pneumoconiosis*, made under the US *Federal Mine Safety and Health Act of 1977*, as amended, PL 95-164. There, it is specified that the diagnosis of pneumoconiosis must be based on the ILO-U/C 1971 classification scheme for chest X-rays, and on defined standards for the interpretation of pulmonary function tests.[16] In this regard, council would also note that a joint task force of the Department of National Health and Welfare and the Canadian Thoracic Society has recommended that the ILO-U/C 1971 classification scheme and an impairment table be employed to interpret the results of chest X-rays, pulmonary function tests and respiratory questionnaires.[17]

Council also believes that the code for medical surveillance should contain guidelines to assist plant physicians in determining whether a worker's health could deteriorate as a result of further exposure to asbestos. In council's view, such guidelines are necessary to ensure that criteria for removal will be consistent from plant to plant. The guidelines developed should address the following issues: i) Can it generally be assumed that a worker's asbestotic condition will not be aggravated at the exposure levels set out in the proposed regulation? ii) In removal decisions, what weight should be accorded to the wishes of a worker? iii) What is meant by the term 'fit with limitations' in the context of asbestos exposures? iv) What appeal mechanisms will be available to workers and employers who disagree with removal decisions?

It is also council's view that policy guidelines must be promulgated to address the question of whether a worker who is removed from an asbestos exposure environment will be entitled to workmen's compensation benefits. Although council understands that Professor Weiler will be examining the general question of compensation for industrial disease in the second phase of his inquiry, members nonetheless believe that the ministry should formulate a general position on the issue of rate retention before the final asbestos regulation is enacted. Such a policy should, in council's view, deal with the following questions:
i) Will a worker be entitled to compensation for lost income when he or she is removed from an asbestos job site and is unable to obtain comparable employment? ii) Will a worker who is not disabled, but is, nonetheless, removed from asbestos employment, be entitled to retraining at the expense of the Workmen's Compensation Board?
iii) What consequences will accrue to a worker when a plant physician and the WCB cannot agree on the question of whether the worker should be removed from work?

In view of the many complexities that seem to pervade decisions on diagnoses, fitness for work and rate retention, council suggests that the minister give consideration to establishing a task group to determine whether the provisions contained in the code for medical surveillance (and in related WCB policy) could be refined to better address the concerns set out in this section. Ideally, the task group should be composed of representatives from physician, labour and management groups as well as of officials from the Ministry of Labour and the Workmen's Compensation Board.

j) *The Continuing Surveillance of an Asbestos Exposed Worker After the Worker has Left His or Her Place of Employment*

During the June 4 meeting, task force members sought the ministry's view on the question of whether a program of continuing health surveillance would benefit those asbestos workers who, for one reason or another, had left their original places of employment. In addressing this issue, ministry officials indicated that most of the asbestos exposed workers in the jurisdiction (and some former asbestos employees) are already subject to government sponsored health surveillance programs. The ministry doubted, however, whether the continuing surveillance of asymptomatic workers was worthwhile and, in any event, thought that it would be impossible to arrange for the cyclical surveillance of all employees who had ever been exposed to asbestos. Ministry officials emphasized that when a worker leaves an asbestos job site, he or she should be i) informed of past exposures to asbestos, and ii) told to communicate this fact to a family physician.

While council shares the ministry's view that follow-up surveillance for all ex-asbestos workers would not be productive, council believes that there may be specific classes of former asbestos employees (e.g. those who have received high cumulative exposures or those who have worked with crocidolite) for whom continuing surveillance might have some benefit. In this respect, it might be desirable for the ministry, in consultation with interested groups, to identify workers who are 'at risk' and to develop suitable health surveillance protocols for them.

CONCLUSION

In previous advisory memoranda, council has observed that the development of occupational health regulations is a difficult and complex task, particularly in the context of an open consultative process. In the case of the proposed interim asbestos standard, it is clear that the dialogue conducted between the ministry and members of the public has caused important and beneficial changes to be made to the regulation and codes. Council also very much appreciates the open attitude taken by ministry officials with respect to the questions raised by its Task Force on Regulations.

On the basis of council's review of the analytical process, it would appear that the rationale employed to set exposure levels for asbestos differs from the regulatory approach taken to establish a control level for vinyl chloride. In the case of vinyl chloride, a Time-Weighted Average Exposure Limit was selected that might theoretically produce a level of excess cancer risk equivalent to that accepted by the International Commission on Radiological

Protection (ICRP) (i.e. 50 excess tumours per year per 100,000 workers). For asbestos, on the other hand, the ministry has adopted the exposure levels recommended by the British Advisory Committee on Asbestos. It would appear, however, that the 1.0 f/cm³ TWAEL for chrysotile proposed by the advisory committee might produce an excess cancer risk of one to two per cent, a level that is comparable to the acceptable risk estimate specified under the ICRP model. Therefore, in the case of both asbestos and vinyl chloride, the exposure levels selected may produce roughly similar levels of excess cancer risk.

In Advisory Memorandum 82-I on vinyl chloride, council noted that the ministry and members of the public had not engaged in any discussion on the general issue of acceptable risk. Council, therefore, made the suggestion that the minister consider the option of holding further public dialogue to canvass this key regulatory topic more thoroughly. The same recommendation could apply equally in the case of the proposed asbestos standard, where public briefs have not focused on the acceptable risk issue. Council believes that further public discussion would be particularly useful since the ministry has stated that it is ultimately for the public and politicians to judge whether a particular level of risk is acceptable.

In council's view, the ministry, in choosing to base its interim exposure levels on the recommendations of the British advisory committee, has adopted one of a series of options available to it. Council must note, however, that the ministry has taken somewhat of a selective approach to the recommendations contained in the BACOA report. While adopting the committee's advice on exposure levels for chrysotile, amosite and crocidolite, the ministry has chosen not to follow other key recommendations propounded in the report (e.g. the requirement that all exposures to asbestos dust be reduced to the minimum that is reasonably practicable,[18] the stipulation that the import of raw crocidolite and products containing crocidolite be prohibited,[19] and the requirement that asbestos users consider the feasibility of employing substitute materials[20]).

Although the ministry has generated some information on asbestos exposures in Ontario worksites, the comprehensiveness of the data is such that one cannot state with confidence what percentage of firms are achieving the 1.0 f/cm³ exposure level for chrysotile on a time-weighted basis or are actually controlling exposures at lower levels. Council has already suggested, in Advisory Memorandum 81-I on lead, that data on workplace exposures should be collected and disseminated at an early stage in the standard setting process to help determine whether it would be easy or difficult for industries to comply with a series of proposed exposure levels.

Council has also expressed the view that the Code for Medical Surveillance for Asbestos Exposed Workers should address a number of important issues that are linked to decisions on worker removal.

To conclude, council as a whole wishes to compliment the ministry for taking the initiative to promulgate an interim standard for asbestos. Council recognizes that the formulation of an interim regulatory strategy is a complex task, particularly since a royal commission will shortly be providing advice on mechanisms for the control of asbestos exposures in the jurisdiction. While some parties may not be satisfied with the contents of the interim standard, council recognizes the sincere desire of the ministry to provide asbestos workers with a more comprehensive level of health protection in a timely fashion. The approach taken would appear to fulfil this objective.

Council looks forward to receiving the final asbestos regulation from the ministry as well as the ministry's analysis of the recommendations to be developed by the Royal Commission on Asbestos.

Footnotes

1. Ontario Ministry of Labour, Occupational Health and Safety Division. The Report on the Designation of Asbestos in Ontario. January 1982, p. G.21.
2. British Advisory Committee on Asbestos. Final Report of the Advisory Committee, vol. 1, pp.74, 77, 78.
3. American Conference of Governmental Industrial Hygienists. Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment with Intended Changes for 1981. Cincinnati, Ohio.
4. American Conference of Governmental Industrial Hygienists. Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment with Intended Changes for 1979. Cincinnati, Ohio, p.50-51.
5. See minister's letter dated March 30, 1982, p.2, which appears as Appendix I to this advisory memorandum.
6. British Advisory Committee on Asbestos, *op. cit.*, p.73.
7. Fourth Annual Report of the Advisory Council on Occupational Health and Occupational Safety. Toronto, p.31.
8. An asbestos fibre is there defined simply as a 'fibre longer than 5 micrometres' (s. 1910.1001, para. 2).
9. Other classes of teachers are already covered under the provisions of the *Occupational Health and Safety Act.*
10. First Annual Report of the Advisory Council on Occupational Health and Occupational Safety. p.43.
11. Third Annual Report of the Advisory Council on Occupational Health and Occupational Safety. p.188.
12. International Labour Organization, Union internationale contre le cancer/Cincinnati (ILO U/C). 1971 International Classification of Radiographs of Pneumoconiosis. Occupational Health and Safety Series 22 (rev.) (Geneva, Switzerland, 1972).
13. On this point see F.D.K. Liddell *et al.*, 'Radiological Findings as Predicators of Mortality in Quebec Asbestos Workers'. In: British Journal of Industrial Medicine, 37, 1980, p.257, and G.L. Ostiguay, 'Summary of Task Force Report on Occupational Respiratory Disease (Pneumoconiosis)'. In: Canadian Medical Association Journal, vol. 121, Aug. 18, 1979, p.421.
14. See, for example, US Department of Labour, 'Standards for Determining Coal Miners' Total Disability or Death Due to Pneumoconiosis'. In: Federal Register, vol. 45, no. 42, Friday, Feb. 29, 1980, S.718.103(a), p.13681, and G.L. Ostiguay, *op. cit.*, p.421.

15. M.R. Becklake *et al*., 'Radiological Changes After Withdrawal From Asbestos Exposure'. In: British Journal of Industrial Medicine, vol. 36, 1979, pp.23,26.
16. US Department of Labour, *op. cit*., S.718.102, p.13680; S.718.103, p.13681.
17. G.L. Ostiguay, *op cit*., p.421.
18. British Advisory Committee on Asbestos, *op. cit*., p.73.
19. *Ibid*., p. 69.
20. *Ibid*., p. 71.

APPENDIX I

Ontario

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March 30, 1982

J. F. Mustard, M.D.
Chairman,
Advisory Council on Occupational
Health and Occupational Safety
15th Floor
400 University Avenue
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Dear Dr. Mustard:

I am pleased to forward the proposed asbestos regulation to the Advisory Council for its consideration. The Ministry was presented with reasoned argument in favour of reducing the exposure limit for chrysotile asbestos from 1 fibre per cubic centimetre to 0.5 fibre per cubic centimetre. The Occupational Health and Safety Division has considered the matter and advises me as follows:

> The Ontario guideline was and indeed still is set at 2 fibres/cc. In August, 1980, based upon the advice from Special Studies and Services Branch (Dr. Finkelstein's report of August 21, 1978, Appendix G, pp. 1-19) and consideration of control limits adopted in other jurisdictions, the proposed regulation for asbestos was published with the following time-weighted average exposure values:
>
> "in the case of amosite, 0.5 fibres/cc of air,
>
> in the case of crocidolite, 0.2 fibres/cc of air, and
>
> in the case of a chrysotile or any other asbestos except amosite and crocidolite, 1.0 fibres/cc of air."

...../2

The problem of setting an occupational standard for asbestos was acknowledged and discussed in the Special Studies and Services Branch document and it was stated that 'from a health point of view, this standard should be set as low as possible'. It was indicated that setting a standard of 1 - 2 fibres/cc might produce an excess cancer risk of 1 - 2% over 25 years exposure which was comparable to the risk posed to radiation workers by the current occupational standards for radiation exposure. Reaction to publication of the exposure values in the 1980 version of the proposed regulation was as expected: industry argued in favour of the continued use of the Ontario guideline (2 fibres/cc) whereas organised labour favoured more stringent values than those published.

A second Special Studies and Services Branch document (Dr. Finkelstein's report of August 28, 1981, Appendix G pp 20 - 49) was prepared to supplement the original and provide a critical appraisal of current information. The document contains a recommendation (p G 31) that 'the occupational standard for exposure to chrysotile, crocidolite and amosite asbestos be set no higher than 0.5 fibres/cm^3 as a time-weighted average for a 40-hour week'. Also, 'it is recommended that the ALARA* principle be applied and that efforts be maintained to decrease exposures wherever feasible'. There is recognition that economic and social criteria are factors in selection of an occupational standard.

It should be mentioned also that compounding the problem of assessing epidemiological data was the lack of precise contemporary exposure data. There are still some problems and some persistent controversy about assessment of exposure to asbestos because the widely used counting procedure is limited by the resolution of the optical microscope. This necessarily restricts the number of fibres counted to those that are visible and fibre identity is not established by this procedure.

It was against this background and the accumulating data, occurring both from continued study by Special Studies and Services Branch and the activities of the Royal Commission on Asbestos, that the exposure limits have been further scrutinised and discussed.

---

*ALARA - as low as reasonably achievable.

...../3

We have had considerable discussion as to the weight to be attributed to the more refined epidemiological study that has been carried out by Dr. Finkelstein. There is every indication that his recent studies, which have so far been subjected to peer review on a somewhat limited basis, will find widespread acceptance. These studies provided the basis for the recommendation for 0.5 fibres/cm^3 as the time-weighted average exposure for a 40-hour week.

There can be little doubt that there is a need to provide protection to the Ontario workforce against exposure to asbestos by means of an enforceable regulation. At this time, it is practical and feasible to proceed with the proposed regulation as presented at the September 22, 1981 meeting.

However, it must be recognised that a recommendation for a more conservative exposure limit such as that based on Dr. Finkelstein's work, part of which has not been published, may be endorsed as a result of the exhaustive enquiries still being pursued by the Royal Commission on Asbestos.

There has been extensive discussion within the Division and there is consensus that it would be prudent to proceed with the regulation and the exposure values contained in the September 22, 1981 version i.e. 1 fibre per cm^3 for chrysotile asbestos; 0.5 fibre per cm^3 for amosite asbestos; and 0.2 fibre per cm^3 for crocidolite asbestos. This will ensure that a further measure of protection is accorded to the workforce of the Province pending further review of Dr. Finkelstein's latest study, and the receipt of the report of the Royal Commission on Asbestos, which is expected before the end of the year.

After careful consideration, I concur with this advice.

I look forward to receiving the Council's advice in the near future.

Yours sincerely

R. H. Ramsey
Minister

APPENDIX II

Agenda for Discussion

1. *The Time-Weighted Average Exposure Levels (TWAELs) Set for Workers Exposed to Asbestos*

   The task force would like to discuss with ministry officials the reasons for not following the recommendation contained in Dr. Finkelstein's report to the effect that the TWAEL for worker exposure to all forms of asbestos should be set at 0.5 f/cm^3.

2. *Maximum Exposure Concentrations*

   It is unclear from the background materials why the ministry chose to increase the maximum exposure limit for amosite from 2.0 f/cm^3 to 2.5 f/cm^3, and to reduce the maximum exposure limit for crocidolite from 2.0 f/cm^3 to 1.0 f/cm^3. Could the ministry elaborate upon the reasons for these changes?

3. *Acceptable Risk and the ALARA Principle*

   In the minister's letter dated March 30, 1982, it is stated that an asbestos exposure level of 1-2 f/cm^3 might produce an excess cancer risk of one to two per cent for workers exposed to the substance over a 25-year period. The task force would like to explore two points with ministry officials:

   a) on what basis has the ministry determined that a possible one to two per cent excess risk of cancer caused by worker exposure to asbestos is acceptable; and
   b) why has the ALARA philosophy not been adopted in the proposed regulation?

4. *The Exposure Levels for Asbestos Currently Being Achieved in Ontario Worksites*

   On pages 6-13 to 6-14 of the background materials, the ministry indicates that 'many companies [in the province] are consistently achieving levels well below 1.0 f/cm^3.' Could the ministry set out for the task force i) the actual percentage of companies in the jurisdiction that are surpassing the 1.0 f/cm^3 standard, and ii) the percentage of asbestos workers who are exposed to TWAELs below 1.0 f/cm^3?

5. *The Costs to Industry of Meeting Interim Exposure Limits*

   The task force would like to hear discussion on the following point: What extra costs will be imposed on industry by the policy of promulgating an interim exposure limit and, shortly thereafter, possibly establishing a different exposure level based on the advice of the royal commission?

6. *Alternative Policy Approaches for the Control of Asbestos Exposures*

Could ministry officials discuss with task force members the reasons for not including in the proposed regulation a) a provision requiring that asbestos substitutes be employed in the jurisdiction, wherever feasible, b) a statutory ban on the use of certain types of asbestos (e.g. crocidolite), and c) a statutory ban on the non-essential uses of all forms of asbestos?

7. *The Definition of the Term Asbestos Fibre*

Could the ministry explain, for the benefit of task force members, the reasons why the definition of asbestos fibre contained in the proposed regulation differs from the definition found in the U.S. Asbestos Standard, where an asbestos fibre is defined merely as a 'fibre longer than 5 micrometres'? (s.1910.1001, para. 2).

8. *Training Programs for Supervisors and Workers Employed in Asbestos Job Sites*

Council would like to explore the ministry's reasons for not requiring, under sub-section 7(2) of the proposed regulation, that formal training programs on asbestos hazards be instituted for supervisors and workers, when a similar sort of provision has been incorporated into subsection 7(2) of the proposed regulation on coke oven emissions.

9. *Asbestos Exposure in Educational Institutions*

Could the ministry elaborate on its reasons for not making the proposed regulation on asbestos apply to teachers or academic staff employed in educational institutions?

10. *The Requirement for an Asbestos Control Program*

Under sub-section 7(1) of the proposed asbestos regulation, an employer must institute an asbestos control program when a workplace assessment discloses a) that a worker is likely to inhale or ingest asbestos, and b) that the health of the worker may be affected thereby. Could the ministry state whether it plans to issue more detailed guidelines to assist labour and management representatives in determining whether an asbestos control program must be put into place in situations where asbestos concentrations are below the TWAEL?

11. *Asbestos Control Programs and the Role of Joint Health and Safety Committees*

On page 2.8 of the background materials, the ministry states that office workers employed in buildings where a) asbestos sheets have been used for walls, floors and ceilings, and b) asbestos has been utilized to coat ceilings, are at risk of asbestos exposure. The task force notes that under section 8 of the *Occupational Health and Safety Act*, an office workplace is not required to have a joint health and safety committee unless so ordered by the minister. In the event that a workplace assessment conducted pursuant to section 6 of the asbestos regulation discloses that an office worker is likely to inhale asbestos and that his health will be affected thereby, what will the ministry's policy be in respect to the question of whether a joint health and safety committee must be established in the affected workplace?

12. *The Medical Removal of an Employee from an Asbestos Work Area*

Under sub-section 4(3) of the Code for Medical Surveillance of Asbestos Exposed Workers, a physician (once he has detected signs of asbestos-induced disease in a worker and after consulting with the Ministry of Labour and the WCB) must determine whether the worker is fit, fit with limitations or unfit for continued work in an asbestos work area. On the basis that asbestosis is a progressive disease and that removal from work may not, therefore, have a measurable effect on the course of the disease, the task force wonders whether there is a need to include a set of general guidelines in the code to assist physicians in making judgements about continued fitness for work. More particularly, should criteria be established to help physicans identify those situations (as defined by the results of X-rays or pulmonary function tests) a) when further asbestos exposure might cause an initial deterioration in the health of a worker, and b) when it would be imprudent to permit a worker already suffering from an asbestos-related disease to continue to be exposed to the fibre?

13. *The Doctor-Patient Relationship in the Context of Government Mandated Health Surveillance Programs*

The task force would like to hear the ministry's view on the question of whether a doctor-patient relationship exists between a) physicians conducting or supervising physical examinations and clinical tests mandated under designated substances regulations and b) workers who participate in such health surveillance programs.

14. *Access by Researchers to Exposure Records That are Made Part of a Worker's Medical Record*

The task force would like to discuss with ministry officials the question of whether exposure records that, by virtue of sub-section 14(2) of the proposed regulation, are made part of a worker's medical record will be readily accessible to accredited researchers or whether the requirements of medical confidentiality will apply. Task force members would also like to explore the issue of whether it might be appropriate to establish a central repository for asbestos exposure records.

15. *The Continuing Surveillance of an Asbestos Worker After the Worker Has Left His Original Place of Employment*

The task force would like to obtain the ministry's views on two points. First, is it felt that a program of continuing health surveillance for asbestos exposed workers would be beneficial to those workers who have, for one reason or another, left their original places of employment? Second, if such a program is judged to be desirable, should it be mandated under the proposed asbestos regulation?

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January 4,1983.

J. Fraser Mustard, M.D.,
Chairman
Advisory Council on Occupational
Health and Occupational Safety
15th Floor
400 University Avenue
Toronto, Ontario
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Dear Dr. Mustard:

Dr. Wolfson, Vice-Chairman of Council submitted on behalf of the Council Advisory Memorandum 82-III on the proposed regulation respecting abestos. I appreciate Council's advice. I was pleased to note that Council recognizes the efforts that have been made by my officials to make possible extensive public participation in the consultative process for the development of occupational health regulations.

I have reviewed Council's response with my officials and I attach their comments on the significant matters raised in your memorandum. The Ministry has deliberately refrained from commenting on points dealt with in replies to previous advisory memoranda on other designated substance regulations.

I would emphasize that the regulation will receive careful review in the light of the report of the Royal Commission on Asbestos expected in 1983.

Please thank Council members on my behalf for their diligent effort and incisive analysis.

Yours truly

R. H. Ramsay
Minister

attachment

Ministry of Labour Comments on Advisory Memorandum 82-III December 29, 1982

1. The Rationale for the Choice of the Maximum Exposure Limits (MELs)

The basis for the maximum exposure limits established in sub-section 4(2) was questioned in Advisory Memorandum 82-III. As the ministry noted at its June meeting with council's Task Force on Regulations, the approach adopted by the American Conference of Industrial Hygienists was considered in establishing the maximum exposure limits for asbestos fibres, and the maximum values for exposure in other jurisdictions were reviewed. Following publication of the proposed regulation in August 1980, the ministry reviewed again the scientific basis for the maximum exposure limit. The approach adopted was to modify these limits so that they would be internally consistent, and the concentrations were revised so that each was a factor of five greater than the time-weighted average exposure limit. This is consistent with the previous practice of the ministry. The ministry is prepared to reconsider this matter in the light of the royal commission report expected in 1983.

2. Risk Assessments and the Requirement to Keep Asbestos Concentrations as Low as is Reasonably Practical

The advisory council has drawn attention to the importance of public discussion of the level of risk associated with the 1 fibre/m^3 limit for chrysotile. As the council has pointed out, public consultation on this matter would be more useful following the publication of the report of the Royal Commission on Asbestos. Nonetheless, in recognition that a 1 fibre/cm^3 limit carried some risk to workers, the ministry has included a provision in sub-section 4(1) of the regulation requiring employers to maintain fibre concentrations as low as practical, but not to exceed the 1 fibre/cm^3 limit. As the council noted, this is in keeping with the policy recommended by the British Advisory Committee on Asbestos and the practice of the United Kingdom's Health and Safety Executive. Moreover, the council is aware of the interim nature of this regulation and that the exposure limit will receive careful study following the submission of the report of the Royal Commission on Asbestos.

3. Application of Regulation to Office Workers

Council is correct in its interpretation of section 8 of the Act. Section 8 governs the requirements for the establishment of joint health and safety committees. Sub-section 8(1) lists various workplaces, including offices, in which employers are not required to set up joint committees. The mandatory establishment of committees is governed by sub-section 8(2) and employers are required to establish committees in workplaces where designated substances regulations apply, except where the exemption of sub-section 8(1) takes precedence.

However, it should be noted that sub-section 8(1) is subject to sub-section 8(3), which allows the minister to order the establishment of one or more committees in any of the workplaces exempted by sub-section 8(1).

Similarly, sub-section 8(2) is subject to sub-section 8(3). Thus, the minister could order a committee to be established in an office.

Council is correct in pointing out that the power of the minister under sub-section 8(3), to override the exemption to the requirement of establishing any committee given under sub-section 8(1), is not limited in any way by sub-section 8(4). That sub-section merely lists factors that the minister 'shall consider' in exercising his power, and one of the factors is whether or not there is a request by either of the parties for a committee. However, the existence of such a request is not a condition precedent to the exercise of the minister's power under sub-section 8(3). In the case of an office, the minister would take into account the presence of asbestos and the extent of worker exposure.

4. Asbestos Register

Officials of the Occupational Health and Safety Division would be pleased to discuss further with council the establishment of a central register for those occupationally exposed to toxic agents. While there is no requirement in any of the designated substance regulations for a central repository of worker exposure data at this time, the value of such a repository for purposes of epidemiological research is recognised.

The council referred to the policy of the Construction Health and Safety Branch requesting employers to provide lists of names of workers exposed to asbestos and especially those engaged in removal or demolition projects. This is a practice encouraged by the branch and is included as a requirement in the proposed asbestos regulation for construction projects.

5. The Removal of an Employee from an Asbestos Work Area on Medical Advice

The council is concerned about the uniform application diagnostic criteria. The Code for Medical Surveillance of Asbestos Exposed Workers requires the interpretation of X-rays by a radiologist or chest physician proficient in reading chest radiographs in accordance with the ILO, 1980 Code. A grading of 1/1 for irregular opacities is used as supportive evidence, with the appropriate clinical findings and medical and occupational histories, for diagnosis of pneumoconiosis and asbestosis.

In addition, the Medical Code also requires that instruments for pulmonary function tests be calibrated to current standards as published in the 'Snowbird Workshop on Standardization of Spirometry', *American Review of Respiratory Illness*, VI. 119, 831-838, 1979.

The council also suggested the need to specify criteria to assist physicians to determine when a worker is suffering from a job-related disease and when further exposure to a toxic agent is likely to cause a deterioration of health.

The ministry does not agree that it is appropriate to include in the Code for Medical Surveillance of Asbestos Exposed Workers guidelines for the removal of workers exposed to asbestos where X-rays show lung abnormalities and the examining physician considers the worker to be 'fit with limitations' or 'unfit' to work in asbestos exposure. Each case must be considered on its own merits taking into account factors such as:

- the age of the worker;
- the extent of the disease;
- the nature of the work; and
- the degree of asbestos exposure.

It should be noted that provisions have been included in the Code for Medical Surveillance that would prevent a worker being removed from exposure to asbestos without prior consultation with the Workers' Compensation Board and the Chest Disease Service of the Ministry of Labour. This provides a further opportunity for external advice to the examining physician on the need for removal.

Finally, the advisory memorandum addresses the issue of earnings retention and the role of the Workers' Compensation Board. The council has set out several important policy questions that are currently under review by the Royal Commission on Asbestos, and by Professor Paul Weiler, who is reviewing the workers' compensation system. The ministry will consider council's advice further following receipt of these two reports.

6. The Continuing Surveillance of an Asbestos Exposed Worker After the Worker has Left His or Her Place of Employment

The ministry is receptive to the suggestion that some feasible and practical arrangements should be explored to ensure that workers leaving the asbestos industry should be subject to continuing medical surveillance. However, it is difficult to impose such a requirement in a regulation that presupposes a continuous employment relationship and places obligations on employers in relation to employees in the active work force.

However, apart from the designated substances approach, the ministry would consider a practical arrangement to deal with this matter. It should be noted that the code for medical surveillance has been modified to require that workers leaving employment are advised to inform their family physician of their history of occupational exposure to asbestos whenever they undergo a medical examination.

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February 22, 1983.

Dr. J.F. Mustard,
Chairman,
Advisory Council on Occupational Health
and Occupational Safety,
400 University Avenue,
15th Floor,
Toronto, Ontario.

Dear Dr. Mustard:

I wish to advise you of a recent issue which has arisen with respect to the Asbestos Regulation, O. Reg. 570/82, and to seek the guidance of Council.

As you know, the Asbestos Regulation defines asbestos as "any of the following fibrous silicates: actinolite, amosite, anthophyllite, chrysotile, crocidolite and tremolite" (emphasis added). A fibre is defined as, "a fibre of asbestos that is more than five micrometres in length and less than three micrometres in width and that has a length to width ratio not less than three to one as viewed in a phase contrast optical microscope at four hundred to five hundred magnifications".

As I understand it, all of the six listed silicates occur in nature in two habits, a crystalline habit and a fibrous or asbestiform habit. Chrysotile, crocidolite and amosite are the names given to three of these silicates when they occur in fibrous habit. However, for actinolite, anthophyllite, and tremolite there is no unique name assigned to the silicate when it occurs in a fibrous habit. Therefore the term tremolite, for example, includes the silicate in both its fibrous and non-fibrous habit.

In the natural state the distinction between fibrous and non-fibrous habit is relatively easy to make. However, in their various industrial uses the silicates can be crushed into fine dusts which, when viewed under a phase contrast optical microscope, meet the size and shape requirements of a fibre as prescribed in the regulation. A more sophisticated analysis can determine which of the six listed silicates is present but, for all of the silicates except chrysotile it cannot determine, with certainty, whether the silicate was originally fibrous or crystalline.

The specific circumstances in which this problem came to light involves the tremolite content in talc. Analysis of samples of talc by the Occupational Health Laboratory has disclosed particles of tremolite which have the requisite size and shape to constitute a fibre. It was intended by the Occupational Health Branch that the Asbestos Regulation would apply in such a situation. However, the producers of the talc maintain that the tremolite in their product originates in a crystalline habit. Since the tremolite was non-fibrous in habit, they maintain that the regulation does not apply. We are continuing to study the legal question, namely, whether the words "fibrous silicate" in the definition of asbestos require that the silicate be in a fibrous habit in the natural state.

Due to the difficult scientific and medical aspects of the problem it has been decided that further expert investigation is warranted. It would be appreciated if you would advise me whether the Advisory Council is prepared to convene a panel of experts to consider the problem and prepare a report for my consideration.

The Ministry would be grateful if the following questions could be addressed:

(1) Is there adequate evidence to correlate exposure of 'fibres', derived from silicates of the asbestos group that occur in the crystalline form, with adverse effects on health?

(2) Do the known, suspected or predicted effects on health of exposure to such fibres warrant control under the Asbestos Regulation or should a 'mineral fibre' regulation be developed?

There is some urgency to this request as the lack of a definitive answer may interfere with the administration of the Asbestos Regulation. Therefore, I would appreciate hearing your views as soon as possible on the willingness of Council to undertake such a task.

Yours sincerely,

R. H. Ramsay,
Minister.

Ontario

Advisory Council on
Occupational Health &
Occupational Safety

Office
of the
Chairman

400 University Avenue
Toronto, Ontario
M7A 1T7

416/965-2448

March 18, 1983

The Honourable Russell H. Ramsay,
Minister of Labour,
400 University Avenue,
14th Floor,
TORONTO, Ontario.

Dear Mr. Minister:

On March 8, the advisory council discussed your letter dated February 22, in which you asked whether council might be willing to convene an expert panel to a) investigate the adverse health effects associated with exposure to asbestos fibres that occur in the crystalline form, and b) advise on the most appropriate legal mechanism through which exposure to such fibres could be controlled. Council believes, in the first instance, that this matter should be referred to the Royal Commission on Asbestos which has been examining, in considerable detail, the health effects induced by exposure to asbestos. In the event that the Royal Commission has not considered the questions now posed by the ministry, an alternative investigative arrangement may need to be considered.

In the view of council members, the issues raised in the February 22 letter relate to the question of whether there is a need to develop new regulatory provisions in order to control worker exposure to an agent that could possibly be hazardous to health. Council would note that ministry officials have acquired a great deal of experience in resolving issues of this nature. In this respect, council believes that it would be entirely appropriate for your staff, possibly with the aid of outside experts, to deal with the concerns raised in the February 22 letter. As has been the custom in the past, council would be pleased to review the process by which any new occupational health regulation is developed.

Please be advised that the chairman of the advisory council took no part in these deliberations since he also sits as a member of the Royal Commission on Asbestos. Since I chaired the portion of the meeting at which your letter was discussed, it was thought appropriate that I should convey council's comments to you.

Yours truly,

Carolyn Tuohy

Dr. C. J. Tuohy

(on behalf of the
Advisory Council)

cc to: T. E. Armstrong, Q.C.
Dr. A. E. Robinson

Ontario

Office of the Minister

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of
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400 University Avenue
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March 25th, 1983

Dr. C. J. Tuohy,
Office of the Chairman,
Advisory Council on Occupational
  Health & Occupational Safety,
400 University Avenue, 15th Floor,
Toronto, Ontario
M7A 1T7

Dear Dr. Tuohy,

Thank you for your letter of March 18th in reply to my letter of February 22nd, concerning talc and the Regulation respecting Asbestos. While I appreciate your suggestions, for the reasons outlined below, I had considered and rejected the options that you had set forth in your letter before I wrote to you.

As I indicated in my letter of February 22nd, certain producers of talc maintain that the tremolite in their product originates in a crystalline habit, and that therefore the Asbestos Regulation does not apply. The Ministry requires an expert scientific opinion on the toxicity of crystalline talc. While it is true that this could be provided by members of staff, I am firmly of the view that an impartial source of scientific advice is most important. As a result I determined that an objective external opinion was necessary.

I considered the possibility of referring the matter to the Royal Commission on Asbestos, however I understand that the hearings of the Commission are now complete, and that in fact the Commission is presently writing its report.

For the reasons outlined in this letter and my letter of February 22nd then, I concluded that it was appropriate for me to request the assistance of Advisory Council in obtaining this opinion for me. Might I suggest that Council establish a task force of experts, nominated by it, to present its report to me through Council. I should perhaps make it clear that I am content that Council simply transmit the report of its task force to me without considering or endorsing the contents of the report.

- 2 -

I would be grateful if my request were to be placed on the Agenda for Council's forthcoming meeting of April 5th. Thank you in advance for your co-operation.

Yours sincerely,

R.H. Ramsay
Minister

Advisory Memorandum 82-IV

Ontario

Advisory Council on
Occupational Health &
Occupational Safety

Office
of the
Chairman

400 University Avenue
Toronto, Ontario
M7A 1T7

416/965-2448

January 21, 1983

The Hon. R. H. Ramsay
Minister of Labour
400 University Avenue
Toronto, Ontario
M7A 1T7

Dear Mr. Minister:

On behalf of the Advisory Council, I am enclosing Advisory Memorandum 82-IV in which Council has reviewed the process for the development of the noise regulation, in light of the policies and principles set out in Advisory Memorandum 78-II.

Council is pleased to have participated in the process by which the final noise regulation was developed.

Yours truly,

J. F. Mustard, M.D.
Chairman

Encl.

c.c. T. E. Armstrong, Q.C.
Dr. A. E. Robinson

Advisory Memorandum 82-IV
to the Minister of Labour
January 21, 1983

A Review by the Advisory Council of the Process Used to Develop a Standard for Noise and Council's Evaluation of the Criteria Utilized to Assess the Hazard of Noise Exposure in the Workplace

INTRODUCTION

In February 1978, the advisory council and the then Minister of Labour agreed that council should be given the task of reviewing the principles and procedures used in setting occupational health standards and guidelines in Ontario. In Advisory Memorandum 78-II, council set out a list of the basic principles and procedures that should ideally characterize the policy process in respect to establishing standards, guidelines and codes. In this document, council undertook to review the criteria utilized by the Ministry of Labour to evaluate occupational health hazards and to follow the ministry's standard setting process through to its final form. It was also clearly understood that council would limit its review to the process leading to the development of ministry standards. In its memorandum, council also stated that it would require 30 days to complete its review function. In subsequent correspondence with the minister, it was agreed that, because of public interest in the area, council's review of the standard setting process should be submitted in the form of an advisory memorandum.

In June 1980, the Ministry of Labour published a Notice of Intent to designate noise as an agent 'to which the exposure of a worker is prohibited, regulated, restricted, limited or controlled under the *Occupational Health and Safety Act*.' This was followed, in August 1980, by a notice setting forth the ministry's proposed regulation for noise. The notice invited public comments and stipulated that such comments would be made available for public examination. At the same time, the ministry distributed copies of the proposed regulation and an accompanying code for determining noise levels to interested members of the public. In October 1980, the ministry distributed a document entitled *Interim Report on the Designation of Noise in Ontario*. This document dealt with such topics as the extent to which workers in Ontario are exposed to occupational noise, the control of noise emissions and the health effects associated with exposure to noise. Each interim report also contained a copy of the proposed regulation and the attached code. On June 24, 1981, the ministry held a public meeting to discuss changes that had been made to the August 1980 version of the regulation. A revised version of the proposed regulation and attached code were distributed at this time, along with three entirely new codes for hearing protection, audiometry and medical surveillance. Invitees were informed that they would have a short period of time to comment on any revisions that had been made to the regulation and codes. On November 2, 1982, ministry officials held a meeting with a number of industry representatives to discuss the question of whether a three or five-decibel (dB) exchange rate should be utilized for the calculation of average exposures to noise. On November 5, 1982, a similar meeting was convened with a number of representatives from the labour movement.

Following these consultations, the ministry, on November 12, 1982, submitted to the advisory council a revised version of the noise regulation. The covering letter, which accompanied the proposed regulation, is attached as Appendix I. On November 30, 1982, council received from the ministry a three-volume document entitled *The Report on the Designation of Noise in Ontario*. This document contained, among other things, a summary of the views expressed by members of the public on the various provisions contained in the first and second drafts of the regulation. The type of action taken by the ministry in response to the submissions made was also outlined. The background materials supplied to council did not contain an analysis of the type of economic impact that Ontario industry would likely experience if the provisions contained in the proposed noise regulation were implemented.

After an initial review of the revised regulation and accompanying background materials, council asked that a meeting be scheduled between its Task Force on Regulations and ministry officials. The objective of this meeting was to permit task force members to explore, in greater depth, the rationale employed by the ministry to arrive at certain policy decisions. The meeting in question took place on December 8, 1982. The agenda for discussion, which was prepared for this meeting, is reproduced in Appendix II of this advisory memorandum.

On December 30, 1982, the Deputy Minister of Labour requested task force members to attend a second meeting with ministry staff. The purpose of this meeting, which took place on January 5, 1983, was to allow the ministry to clarify some statements that had been made during the meeting of December 8. The letter of the deputy minister is attached as Appendix III.

As was the case in council's review of the process leading to the development of other designated substances regulations, council intends to focus on three aspects of the standard setting process. These are the consultative process (i.e. whether the public was provided with sufficient opportunity to comment upon and participate in the development of the regulation), the analytical process (i.e. whether the ministry assembled, reviewed and analysed the available evidence in a reasonable fashion, and whether the conclusions reached were compatible with the evidence) and the legal-technical process (i.e. whether the regulation and codes are internally consistent, and whether the intent of the ministry has been translated into clear and unambiguous regulatory provisions).

COUNCIL'S REVIEW OF THE STANDARD SETTING PROCESS FOR NOISE

1. The Consultative Process

To reiterate the comments made in previous advisory memoranda, council wishes to commend the ministry on the steps it has taken to make possible public participation in the standard setting process. Council strongly endorses the ministry's efforts to develop an open process for the setting of standards. Council is also cognizant of the special circumstances that surrounded the publication of the first seven designated substances regulations and the difficulty of adhering strictly to the procedures set out by council in Advisory Memorandum 78-II. In this regard, council notes that the former Minister of Labour undertook, in his reply to Advisory Memorandum 81-I on lead, to give serious consideration to a number of suggestions made by council to enhance the quality of the consultative process.

Council wishes to make one additional point that relates to the completeness of the consultative process employed to develop the proposed noise standard. From a review of the latest version of the regulation, it is clear that a number of amendments were made to the standard at a late stage in the regulatory process. In council's view, the most important of these changes were a) the shift to a compliance strategy based on the measurement of sound levels, and b) the exemption of highway vehicles from the application of the regulation. Council wishes to note that the ministry did not indicate, either in its *Interim Report on the Designation of Noise in Ontario* or at the June 24 public meeting, that such changes were being contemplated. On the basis of this observation, task force members asked the ministry to elaborate on the steps that had been taken to obtain public input in respect to these amendments. In response to this question, the ministry indicated that in November 1982, separate meetings were convened with management and labour groups to discuss a) the relative merits of the three and five dB exchange rates, and b) the appropriateness of a monitoring strategy based on the calculation of average exposure to noise. At these meetings, the option of adopting a compliance strategy based on the measurement of sound levels, which the ministry ultimately chose to pursue, was raised. The ministry indicated that while these meetings were not open to the public, the groups that were invited possessed considerable expertise on the subject of noise, and were fully conversant with the exchange rate issue. Ministry officials were also of the opinion that, given the need to promulgate the proposed regulation in an expeditious fashion, this additional degree of consultation was sufficient. In respect to the exemption of highway vehicles from the regulation, the ministry stated that, subsequent to the June 24 public meeting, it had received a brief from the Ontario Trucking Association (OTA) that presented persuasive arguments against having the regulation apply to truck drivers. The ministry then endeavoured to obtain the views of the Teamsters union on this subject. The Teamsters took the position, however, that until their strike was settled, they would not be prepared to discuss the topic of an appropriate noise control strategy with the OTA. The ministry did not indicate that other labour organizations were approached on the exemption issue. On the basis, however, that the drivers of highway vehicles would soon be covered under a separate regulation, the ministry felt that there would be ample opportunity for further dialogue on this subject.

It is clear from the ministry's response that the process of consultation with interested parties was extended beyond the June 24 meeting. In a letter to the former Minister of Labour on the lead regulation, dated May 15, 1981, council has recognized that informal consultation may play a role in the development of occupational health standards. Council has taken the position, however, that it is beyond the scope of its review function to comment on the non-public character of the consultative process. The relevant portion of the May 15 correspondence is worded as follows:

> 'Council recognizes that with our form of government, interested parties may well make representations to government outside of the consultative process. Council does not believe that its review should take into consideration any informal, unsolicited parts of the process as they are the responsibility of the minister and the government . . . If such advocacy leads to major changes, the arguments will, presumably, be made public and the changes explained by the government in association with its final regulation.'[1]

Where, however, changes are made to a regulation as a result of the informal consultative process, council will, as in the case of all materials it reviews, exercise its responsibility to comment on the analytical process, be it the product of formal discussions or otherwise.

In the view of some members of council, the November 1982 meetings should be regarded as adjuncts to the formal consultative process. These members take the view that the ministry, in developing certain portions of the proposed noise standard, has departed from its ordinary practice of a) convening public meetings, and b) discussing important issues in the presence of both labour and management representatives. On this basis, it is felt that the two late changes to the regulation may not have been debated in as thorough a fashion as possible and, therefore, that further public consultation would have been desirable. Other members believe, however, that irrespective of whether the meetings with labour and management are characterized as part of the formal consultative process or not, the degree of public input that has been obtained fully meets the objectives set for the consultative process.

2. The Analytical Process

In reviewing the analytical process used to develop a standard for noise, council's role is to judge how effectively the ministry has assembled, reviewed and analysed the available evidence. In embarking on this task, council has the advantage of examining a complex and difficult process in its final stage. Hence, council is in a position to review not only the arguments put forward by participants, but also the rationale supplied by the ministry for formulating its regulation in a particular fashion in light of the evidence and arguments raised.

As a first step in discharging its responsibilities, members of council's Task Force on Regulations met with ministry officials to seek more complete information on the rationale employed by the ministry to arrive at several important regulatory decisions. The key analytical issues taken up with ministry staff are discussed below.

a) *The Action Level for the Introduction of Engineering Controls to Limit Noise Exposure in the Workplace*

During the meeting with ministry officials conducted on December 8, 1982, task force members asked the ministry to elaborate on its rationale for increasing the action level for the introduction of engineering controls in the workplace from 85 to 90 decibels A-weighted (dBA). In response to this question, ministry officials acknowledged that an 85-dBA action level would be more protective of hearing than the less stringent 90-dBA level. The ministry accepted as realistic the prediction that an additional 10 to 15 per cent of workers exposed to noise during the course of their working lifetimes could suffer hearing impairment at a noise level of 90 dBA, when compared to the 85-dBA level.[2] These figures, the ministry emphasized, are based on the assumption that hearing protection has not been provided, and used by workers. Ministry officials indicated that the decision to increase the action level for the adoption of engineering controls from 85 to 90 dBA was based on essentially three considerations:

i) Submissions received from industry groups to the effect that the adoption of an 85-dBA standard would not be economically or technologically feasible in many cases.
ii) The advice obtained from the advisory council in February 1980.[3]
iii) The fact that the proposed noise regulation will contain other safeguards designed to protect the hearing of workers (e.g. periodic audiometry and the mandatory use of hearing protection).

In pursuing the discussion, task force members asked the ministry to summarize the evidence relied upon for its conclusion that an 85-dBA action level for the implementation of engineering controls would be neither economically nor technologically feasible. In addressing this point, ministry officials indicated that it had been extremely difficult to estimate the percentage of Ontario workers who are occupationally exposed to noise levels of 85 and 90 dBA. The ministry also pointed out that the advisory council had, itself, expressed reservations about the feasibility of achieving an 85-dBA standard through the use of engineering controls. Finally, it was noted that, by virtue of sub-section 5(1) of the proposed regulation, employers will now be required to employ engineering controls to reduce sound levels to the lowest practical level below 90 dBA. In this respect, ministry officials anticipated that many employers would be controlling noise emissions below the 90-dBA action level.

On a related point, task force members wished to know whether the ministry would undertake to assess, on a periodic basis, the desirability of adopting an 85-dBA action level for the introduction of engineering controls. This approach, it was noted, had been recommended by council in its advisory memorandum on occupational hearing loss.[4] In response to this question, ministry officials indicated that each of the exposure limits that the government has so far promulgated is open to review, analysis and adjustment.

The advisory council shares the ministry's conclusion that, from the perspective of hearing conservation, an 85-dBA noise standard would provide greater protection to workers than a standard of 90 dBA. Council understands that it is the ministry's intention, once the proposed noise regulation has been promulgated, to conduct a study that will assess (among other things) the economic costs associated with the choice of a three or five-dB exchange rate. Council wonders whether it would be desirable to expand the scope of this study somewhat in order to determine whether an 85-dBA standard would, in fact, be economically feasible.

b) *Recent Studies on the Health Effects of Noise*

At the December 8 meeting, task force members noted that the health effects document contained in the ministry's background materials was dated March 1, 1979. The task force wished to know whether any important studies had been published since that date that would alter the general conclusions reached in the document. In addressing this point, ministry officials indicated that they had been monitoring the scientific literature and that no new studies have emerged that would challenge the conclusions set out in the background materials. Furthermore, due to the paucity of reliable data on the actual exposure of workers to noise, the ministry did not expect that any high quality epidemiological studies would be published in the future.

c) *The Absence in the Proposed Regulation of a Maximum Exposure Limit (MEL)*

A further point raised during the meeting of December 8 concerned the absence in the proposed regulation of a Maximum Exposure Limit. In addressing this issue, ministry officials indicated that the provisions contained in the present noise regulation should ensure that workers will not be exposed to very high noise levels. It was pointed out, in this regard, that sub-section 5(1) already imposes a strict duty on employers to reduce sound levels to the lowest practical level below 90 dBA. Furthermore, under section 8, workers who are subject to noise levels of 85 dBA or more for a period of four or more hours during a working day must wear hearing protection. The ministry also pointed out that employers are entitled to use administrative controls to reduce cumulative exposures to noise. Ministry officials felt, on the basis of the provisions cited, that the inclusion of a Maximum Exposure Limit in the proposed regulation would be superfluous. The ministry also expressed the view that, if an MEL had been placed in the regulation, some employers might have interpreted this provision as a signal that exposures up to this level would be tolerated. The ministry's objective is rather to ensure that noise in the workplace is reduced to the lowest practical level. Finally, the ministry put forward the view that the adoption of a Maximum Exposure Limit, which is based on an instantaneous sound measurement, could put certain operations out of business.

In commenting on the ministry's response, task force members pointed out that hearing protection can provide only a limited degree of noise attenuation. For example, rock drillers who are subjected to sound levels of 130 dBA might still suffer actual exposures of 115 dBA, even if hearing protection were employed properly. The presence of a Maximum Exposure Limit in the regulation, it was argued, would prevent workers from being exposed to such elevated and potentially dangerous noise levels. Task force members also suggested that, in the absence of an MEL, some employers might be less inclined to modify or replace noisy equipment.

Council is not persuaded that the presence of an ALARA clause (i.e. the duty to reduce sound levels to the lowest practical level below 90 dBA) is necessarily incompatible with the concept of a Maximum Exposure

Limit. Members would note, in this regard, that the vinyl chloride regulation incorporates both these provisions in the same standard. Council shares the view of its task force that in worksites characterized by particularly high levels of noise, protective equipment (even if properly fitted and worn) may not adequately guard against hearing loss. Council would also point out that in the background material that accompanied the proposed regulation, evidence is not presented to suggest that employers would find it difficult to achieve the MELs that had been set out in an earlier version of the noise regulation. In light of these considerations, council wonders whether the ministry might give further thought to its decision not to specify Maximum Exposure Limits in the regulation.

d) *The Use of Sound Level Measurements as the Basis for Determining Compliance with the Proposed Regulation*

During the meeting of December 8, task force members asked the ministry to elaborate on its rationale for shifting from a standard based on the calculation of average exposures to noise to one based on the measurement of sound levels. In addressing this point, ministry officials noted that the previous version of the noise regulation was based on the measurement of continuous sound levels (Leq) averaged over a 40-hour work-week. In addition, the Code for Noise Measurement, which was appended to the regulation, specified that the three-dB halving and doubling rule (also known as the three-dB exchange rate) was to be employed in the calculation of a worker's average exposure to noise. Following the June 1981 public meeting, the ministry received a number of comments that were critical of the monitoring strategy that had been adopted in the regulation. First, a number of industry groups put forward the view that the three-dB exchange rate was too restrictive. It was pointed out, in this respect, that there exists genuine controversy within the scientific community about whether a three or five-dB exchange rate is conceptually valid. Second, several labour groups indicated that, from an administrative and technical point of view, the calculation of average exposures for individual workers would be a complex matter. Third, it was indicated that the factors of accuracy associated with the use of personal dosimeters (the devices utilized to calculate a worker's average exposure to noise) leave much to be desired. On the basis of these objections, the ministry made the decision to convene separate meetings with labour and management groups to discuss the exchange rate issue in greater depth. During their meeting with management representatives, the ministry raised the question of whether compliance with the proposed regulation should be based on the measurement of sound levels. The ministry noted, at this meeting, that the approach being contemplated would be similar to that prescribed under section 144 of the current regulation for industrial establishments. The impression obtained during the discussion was that industry could live with a regulation of this type. This arrangement was then discussed with labour representatives who supported the concept of a standard based on the measurement of sound levels. On the basis of the arguments raised against the use of average exposures in the regulation, and as a result of the meetings held with labour and management groups, the ministry decided to adopt the following strategy. First, as an interim measure, the proposed regulation will provide that sound levels, rather than average exposures, are to be used as the basis for determining compliance with the regulation. Second, the ministry will commission an independent study to ascertain whether control levels should ultimately be based on the calculation of a worker's average exposure to noise or, alternatively, whether the measurement of sound levels should continue to be employed for this purpose. This study will also examine the relative merits of the five versus the three-dB exchange rate.

Council has a number of comments to make in respect to the explanation that the ministry has provided. Council would note initially that the shift from the calculation of average exposures to the measurement of sound levels represents a major change in regulatory strategy. In the process, it would appear that the ministry has created a more stringent noise standard. Council would also point out that, by requiring that engineering controls be introduced at the instant that sound levels reach 90 dBA, it may be anticipated that numerous applications will be brought under sub-section 6(b)(ii) of the regulation (the provision that permits employers to provide hearing protection to workers as a method of complying with the 90-dBA control limit, where it can be shown that the use of engineering controls is not reasonable or practical for the length of time or the frequency of exposure or the nature of the process, operation or work). In this respect, ministry inspectors, who are the officials responsible for deciding whether hearing protection equipment may be employed *in lieu* of other control methods, could face an increased administrative burden.

e) *The Protection that the Proposed Regulation Affords to Employees on Extended Work Shifts*

During the December 8 meeting, task force members asked ministry officials to express their views on the question of whether a regulation based on the measurement of sound levels would provide adequate protection to employees who are required to work 12-hour shifts. In addressing this issue, the ministry indicated that the present version of the regulation is actually more protective of hearing than earlier drafts that have been published, since workers will now be required to wear hearing protection when noise levels are found to exceed 85 dBA for a period of four or more hours in a work-day. In this respect, it was felt that the proposed regulation would provide adequate protection to employees on extended work shifts.

f) *The Application of the Proposed Regulation to the Drivers of Vehicles on Highways*

During the December 8 meeting, task force members asked the ministry to elaborate on the reasons for excluding the drivers of vehicles on highways (predominantly truck drivers) from the application of the proposed noise regulation. In response to this question, the ministry indicated that the decision to exempt this class of workers was based on two considerations. First, it was felt that an industrial type regulation would be extremely difficult to apply and enforce on the open road. Ministry officials pointed out, in this respect, that because of different vehicle designs and driving habits, practical problems arise in assessing the typical amount of noise to which an average trucker is exposed. The ministry also took the position that it would be impractical to require an employer to conduct a separate assessment for each vehicle in his or her fleet. Second, ministry officials felt that the adoption of a 90-dBA action level for the introduction of engineering controls in truck cabs would be neither economically nor technologically feasible, especially for older vehicles, which would require extensive retrofitting. The ministry then reasoned that, since the trucking and construction industries share a number of similar attributes (e.g. workers involved in these activities do not ordinarily remain in the same worksite for an extended period of time), it would be logical to treat these two operations under the same regulatory framework. The ministry indicated, furthermore, that a noise regulation for highway vehicles and construction sites had recently been developed and would soon be gazetted.

On a related point, the task force sought the ministry's rationale for not including in the proposed noise regulation provisions which would require manufacturers and designers to i) ensure, as far as reasonably practicable, that machinery or equipment does not produce noise likely to be injurious to health, and ii) where high levels of noise cannot be engineered out, a requirement that adequate information be provided to users on the noise levels likely to be produced by the article, and the steps that should be taken to minimize exposures. Members noted that similar sorts of provisions were contained in section 7 of the proposed regulation on hearing protection developed by the British Health and Safety Commission.[5] In addressing this point, ministry officials indicated that the *Occupational Health and Safety Act*, unlike the British *Health and Safety at Work Act*, does not permit regulatory provisions to be enacted that would impose obligations on designers and manufacturers. The ministry reasoned, furthermore, that in a jurisdiction such as Ontario, where many industrial products must be imported, it might be difficult to impose obligations of this nature on the suppliers of equipment and machinery.

While council appreciates that the *Occupational Health and Safety Act* imposes restrictions on the class of regulations that may be promulgated, it wishes to point out, as indicated in Advisory Memorandum 79-III on occupational hearing loss, that, in the long term, the most effective approach for reducing sound levels at work is through equipment design and manufacture.[6]

g) *Fitness for Work in a Noise Exposure Environment*

During their meeting with ministry officials, task force members asked why the Code for Medical Surveillance of Noise-Exposed Workers does not contain guidelines to help plant physicians determine when a worker will be considered 'fit with limitations' or 'unfit' for work in a noise exposure environment. In response to this question, ministry officials stated that, as a general rule, workers with hearing loss should not be removed from job sites characterized by high noise levels. While the principle may be clear, the ministry indicated that it would be extremely difficult to develop a single set of criteria to determine when a medical removal would be warranted. The decision must be based on a number of factors, including the nature of the job and the type of hearing loss experienced by the worker. In addition, for certain classes of workers, noise associated hypertension or stress could impose limits on the sorts of tasks that the individual could perform. On this basis, the ministry took the position that the question of medical removal should be left to the judgement of the examining physician.

Council shares the ministry's view that there are few medical justifications for requiring a worker who is suffering from hearing loss to be removed from a noise exposure environment. Members also agree with the ministry that decisions on worker removal must take into account both medical and non-medical factors. Council wonders, however, whether it might not be appropriate to include in the code for medical surveillance i) the general presumption that workers should not be removed from noise exposure job sites, and ii) a list of considerations that could be applied when removal is being contemplated. Factors to consider, in this regard, might include: i) the nature of the hearing loss sustained, ii) whether continued exposure to noise is likely to cause further deterioration in hearing, iii) the requirements of the job, iv) whether a worker's hearing loss is likely to endanger his own safety or the safety of fellow employees, v) the abilities of the individual worker, vi) the availability of alternative employment opportunities within the same organization, and vii) the employee's own wishes. In council's view, the promulgation of such criteria would help to ensure that workers are not removed for inappropriate reasons.

h) *The Ministry's Definition of a 'Significant Threshold Shift'*

Under sub-section 7(2)(m) of the Code for Audiometry of Noise-Exposed Workers, a 'significant threshold shift' is defined as 'a difference of 15 dB at 3,000 or 4,000 Hz compared with either the baseline or previous audiogram.' Members of the task force, noting that certain steps must be taken when a confirmed significant threshold shift has been identified, asked the ministry to elaborate on its reasons for i) selecting 15 dB as the measure of significant threshold shift, and ii) specifying that only two speech frequencies must be considered when threshold shift is measured. In response to the first question, the ministry indicated that, on the basis of the scientific literature that had been reviewed (including a soon-to-be-released study by Royster[7]), the 15-dB 'action level' is a reasonable criterion for identifying workers who exhibit early signs of noise-induced hearing loss. Ministry officials stressed, however, that physicians are also at liberty to apply their own criteria to identify workers who have suffered a significant deterioration in hearing. In addressing the second question, ministry officials pointed out that the U.S. Occupational Safety and Health Administration (OSHA) had recommended that the 15-dB threshold shift be averaged over the 3,000 and 4,000 Hz speech frequencies. The ministry indicated, furthermore, that it had chosen not to follow the recommendation of the American Academy of Otolaryngology, and average audiometric test results over the 500, 1,000, 2,000 and 3,000 Hz frequency range since this formula, while able to identify threshold shifts that will affect the ability to communicate, is less sensitive to the early signs of noise induced hearing loss.

3) The Legal-Technical Process

As a result of dicussions held between the ministry and interested groups, including council's task force, subsequent to the June 24, 1981 public meeting, several changes of a legal or technical nature have been made to the proposed noise regulation and to the accompanying codes. The major amendments are set out below:

i) Sub-section 4(2) of the proposed regulation now provides that an employer's obligation to protect the health of a non-employee will arise when the non-employee is subjected to noise at the employer's worksite. (The previous version of the sub-section had imposed the additional requirement that there must be a likelihood that the health of the worker would be affected by such exposures).

ii) Sub-section 5(2) of the proposed regulation now specifies that the statutory defence made available to an employer under this sub-section will only come into play where the employer can prove a) that a breach of sub-section 5(1)(i.e. the provision which requires that sound levels be reduced to the lowest practical level below 90 dBA through the use of engineering controls) occurred solely because an employee failed to work in compliance with the work practices specified in the hearing conservation program, and b) that the employer has taken every precaution reasonable in the circumstances to require the worker to do so. (The previous version of the regulation merely required that the employer establish non-compliance on the part of a worker).

iii) Sub-section 3(3)(b) of the Code for Medical Surveillance of Noise-Exposed Workers now provides that a physician must refer an employee to the Workers' Compensation Board (WCB) for assessment where the worker has suffered a confirmed hearing loss of 25 dB average at 0.5, 1, 2 and 3 kilohertz (kHz), if the hearing loss is thought to be occupationally induced. (In the previous version of the regulation, the referral of a worker for assessment under these circumstances had been left to the discretion of the plant physician).

iv) Sub-section 3(3)(c) of the Code for Medical Surveillance of Noise-Exposed Workers now specifies that a physician must provide a joint health and safety committee with an annual report that summarizes the results of audiometric tests conducted on workers. (The provision of such a report had not been made mandatory under the previous version of the regulation).

Council wishes to make several additional points in respect to the legal-technical process. Council believes that the following items require further comment.

a) *The Definitions Accorded to the Terms 'Highway' and 'Vehicle' under the Proposed Noise Regulation*

Sub-section 4(3) of the proposed noise regulation specifies that workers in or on vehicles (as defined under the *Highway Traffic Act*) being operated on highways (as defined under the *Highway Traffic Act*) and their employers will be exempted from the provisions contained in the regulation. During the December 8 meeting, task force members pointed out that, by defining the terms 'highway' and 'vehicle' according to the

Highway Traffic Act, problems could arise in respect to the application of the regulation in the field. For example, while a truck and its occupants would be exempted from the proposed noise regulation when the vehicle was being operated on a street or public highway, the regulation *would* apply as soon as the vehicle was driven on to an industrial site (e.g. for the purposes of loading or unloading). On this basis, task force members put two questions to ministry officials. First, why has the ministry chosen to make the proposed noise regulation apply to highway vehicles in some situations, but not in others? Second, to what extent has the ministry considered the administrative difficulties that such an approach might engender? In response to the first question, ministry officials took the position that where a truck or other vehicle is on an industrial worksite, it is reasonable to presume that the employer will be able to determine the level of sound to which a driver is subject. In this respect, the employer can take the steps necessary to protect the hearing of exposed workers. Once a vehicle has left the worksite, however, the employer is no longer in a position to control worker exposure to noise. On the basis of these considerations, the ministry concluded that highway vehicles should be brought under the proposed noise regulation when they operate on industrial sites. In addressing the second point raised by the task force, the ministry acknowledged that there could be some initial confusion in respect to which vehicles would be included or excluded from the regulation. Ministry officials reasoned, however, that a regulatory strategy that exempted all vehicles from the application of the regulation would cause far more serious administrative difficulties. In order to clarify the meaning of the terms 'highway' and 'vehicle', the ministry agreed with the task force that the *Highway Traffic Act* definitions for these terms should be reproduced in the proposed noise regulation.

b) *The Meaning of the Term 'Sound Level of Noise' Contained in Sub-section 5(1) of the Proposed Noise Regulation*

On a further point of clarification, task force members asked the ministry to explain the meaning of the term 'sound level of noise', which is referred to in sub-section 5(1) and other sections of the proposed regulation. In response to this question, the ministry indicated that a sound level of noise refers to a sound level of 80 dBA or above. This hybrid term was included in the regulation to emphasize that the standard is based on the measurement of sound levels and not on the calculation of average exposures for individual workers.

c) *The Duty Placed on Employers to Reduce Sound Levels to the Lowest Practical Level below 90 dBA through the Use of Engineering Controls*

Pursuant to sub-section 5(1) of the proposed noise regulation, an employer (whose workers are subjected to sound levels of noise greater than or equal to 90 dBA) is required to adopt engineering controls to reduce sound levels in a workplace to the lowest practical level below 90 dBA. During their meeting with ministry officials, task force members noted that the employer's duty under this sub-section is a continuing one. That is to say, even though the employer, through the successful application of engineering controls, is able to reduce sound levels below the 90-dBA action level (for example to 86 dBA), he or she will still be obliged to reduce noise further, until the lowest practical level has been attained. The task force pointed out, however, that an employer whose workers are subjected to sound levels just below 90 dBA (for arguments sake, 89 dBA), is not required to adopt any measures by way of engineering controls to lower the levels of sound in the workplace. On this basis, task force members raised the question of whether it is equitable to impose different types of obligations on the two classes of employers that are based solely on the levels of sound that were originally measured in a workplace. In addressing the task force's point, ministry officials acknowledged that there could be a problem with the wording contained in this provision. On this basis, the ministry undertook to determine whether an amendment to the sub-section would be desirable.

d) *Action to be Taken when a Further Assessment Reveals a Significant Decrease in the Levels of Noise Recorded in a Worksite*

Another issued raised by the task force concerned section 13 of the proposed regulation, the provision which requires an employer to conduct a further assessment where a change is made in a workplace that could result in a significant difference in the level of noise to which a worker is exposed. Task force members wished to know what action an employer would be required to take where a section 13 reassessment reveals that the noise levels in a worksite no longer exceed i) 85 dBA for a period of four or more hours in a working day, and ii) 90 dBA for any period of time (the action levels at which a hearing conservation program must initially be established). More particularly, will the employer be entitled to dismantle a hearing conservation program that already exists, or will he continue to be bound by the general duty set out in section 2 of the proposed regulation to reduce noise to the lowest practical level? In response to this question, ministry officials stated that the employer would be entitled to abandon an established hearing conservation program since noise levels had been adequately reduced. The ministry indicated, furthermore, that section 2 should not be construed as a general duty clause. It is rather a statement of intent that should be regarded as a preamble. Ministry officials also emphasized that although a hearing conservation program would no longer be required under these circumstances, employers would still be obliged to conduct periodic assessments of the worksite.

While council understands the basis for the ministry's position, it wishes to point out that section 13 could allow a hearing conservation program to be dismantled, notwithstanding that noise levels in a worksite could still pose a possible threat to hearing. Council would also note that the interpretation being placed on section 13 appears to conflict with the intent of section 2, which states that 'The purpose of this Regulation is the reduction of noise to the lowest practical level so as to afford maximum protection to workers.' Council wishes to note that the U.S. Occupational Safety and Health Administration has addressed the question of reassessments by prescribing that new measurements must be taken 'within 60 days of a change in production, processes, equipment, controls or personnel which may result in *new* [emphasis added] noise exposures at or above a time-weighted average of 85 decibels.'[8]

e) *An Employee's Entitlement to Workers' Compensation Benefits*

A further point raised by the task force concerned the wording contained in sub-section 20(2) of the proposed noise regulation. Under this provision, a worker will be entitled to receive compensation for lost earnings, to the extent provided by the *Workers' Compensation Act*, where the worker is removed from work because of a condition resulting from exposure to noise. Members of the task force expressed the concern that sub-section 20(2) might convey to workers the false impression that noise-induced hearing loss is compensable, whether or not the condition arose as a result of occupational exposures. The suggestion was made, in this respect, that the phrase 'exposure to noise' contained in this sub-section be amended to read 'occupational exposure to noise'. In response to this point, ministry officials indicated that sub-section 20(2) specifies, quite clearly, that an employee's entitlement to workers' compensation will be determined under the provisions of the *Workers' Compensation Act*. On this basis, the ministry felt that the sub-section, as worded, accurately reflected the law.

f) *The Medical Removal of a Worker from a Noise Exposure Environment*

Members of the task force noted that, pursuant to sub-section 3(3)(b) of the Code for Medical Surveillance of Noise-Exposed Workers, 'workers with a confirmed hearing loss of 25-dB average at 0.5, 1, 2 and 3 [kilohertz] kHz in both ears should be referred for [Workers'] Compensation Board [WCB] assessment, if the hearing loss is thought to be occupationally induced'. During the meeting of December 8, the task force asked the ministry to explain:

i) The intended purpose of the WCB assessment (i.e. is the assessment designed to determine eligibility for compensation or to provide a method by which a plant physician can confirm a diagnostic finding)?

ii) The reasons for specifying that a 25-dB average hearing loss must be recorded in *both* ears (rather than in either ear as stated in an earlier version of the code) before a referral can take place.

iii) The rationale for requiring that the WCB assessment be conducted only where a plant physician considers that a worker's hearing loss has been occupationally induced—when this is precisely the issue that the WCB must resolve.

In response to the first question, the ministry indicated that the WCB assessment is designed, primarily, to determine eligibility for workers' compensation benefits. However, the assessment might also produce a more accurate diagnosis of a worker's hearing loss. On a related point, the ministry did not consider it necessary to clarify the purpose of the assessment in the code for medical surveillance.

In addressing the second point, ministry officials indicated that the WCB will not award compensation for hearing loss unless there has been an average threshold shift of 25 dB in both ears for the four frequencies set out in sub-section 3(3)(b). On this basis, the ministry felt that no useful purpose would be served by requiring workers to be referred for assessment where the identified hearing loss is not compensable. Council wishes to make two comments that relate to the ministry's response. First, council would note that the criteria for compensation developed by the Workers' Compensation Board may have little relevance to the question of whether a worker is fit for work in a noise exposure environment. Second, by referencing WCB compensation criteria in the portion of the code that addresses worker removal, there is the risk that some physicians and employers could take the position that a worker must be removed as soon as he has suffered a 25-db hearing loss in both ears.

In replying to the third question, the ministry indicated that if plant physicians were required to refer every worker with a 25-dB hearing loss to the WCB, the board would be inundated with claims. Task force members observed, however, that a provision that makes referral to the WCB depend on the judgement of a plant physician (who might not have expertise in the field of occupational hearing loss) might result in some valid claims not being forwarded to the WCB. In addressing this concern, ministry officials pointed out that a worker, or an employer on his behalf, might file a compensation claim with the board, irrespective of the position taken by the examining physician. The task force noted, however, that many workers are unaware that occupational hearing loss is compensable and, consequently, that they have the right to file compensation claims with the WCB.

Council wonders whether the concerns of the task force could not be addressed by requiring plant physicians to inform employees of their rights to apply for workers' compensation benefits in situations where i) a 25-dB hearing loss has been detected, and ii) the examining physician decides not to refer the employee for assessment to the WCB.

g) *Return to Work*

During the December 8 meeting, task force members asked the ministry why the Code for Medical Surveillance of Noise-Exposed Workers does not deal with the issue of when a worker previously removed from a noise exposure environment might be permitted to return to work. The task force noted, in this regard, that the Code for Medical Surveillance for Vinyl Chloride addresses this question by prescribing that the plant physician must determine when a return to work would be advisable. In response to this question, the ministry indicated that, for vinyl chloride and some other substances, the test results recorded for workers are likely to be reversible. In this respect, it may be assumed that such workers will return to their former employment at some point in the future. For this reason, the ministry found it necessary to specify, within the Code for Medical Surveillance for Vinyl Chloride, that a physician must decide when a worker might be permitted to return to work. In the case of exposure to noise, on the other hand, a permanent threshold shift is an irreversible condition. It would be unlikely, in this respect, that a worker with a marked degree of hearing loss would be regarded as fit for continued work in a noise exposure environment. For this reason, and on the basis that the ministry does not wish to encourage the removal of workers with hearing loss from job sites, it was decided that a return to work provision should not be included in the Code for Medical Surveillance of Noise-Exposed Workers.

While council appreciates the distinction that the ministry is drawing, it wishes to point out that the Code for Medical Surveillance of Workers Exposed to Coke Oven Emissions, which also deals with irreversible health effects, does contain a return to work provision.

h) *The Publication of Codes in the Official Consolidation of Regulations*

The final point raised by the task force during its meeting with ministry officials related to the codes that are annexed to the proposed noise regulation. Members wished to know whether it is the intention of the ministry to have these documents published in the official consolidation of regulations. In addressing this point, ministry officials indicated that the Registrar of Regulations has the ultimate responsibility for determining which documents may be published under the *Regulations Act* in the *Ontario Gazette* and in later official consolidations. To date, the registrar has not acceded to the ministry's request to have the codes gazetted under this statute. The ministry noted, however, that all codes may be examined by the public at Ministry of Labour offices.

Council understands from its own discussions with government officials that codes that are attached to regulations may be gazetted under the Regulations Act, as long as they are reclassified as schedules. Council appreciates that there are difficulties involved in translating the often general and non-mandatory provisions, which codes typically contain, into a format that is suitable for gazetting. At the same time, however, council must point out that the codes that are referenced in the proposed noise regulation have, within them, a number of extremely important provisions. For example, the Code for Medical Surveillance of Noise-Exposed Workers prescribes a number of specific obligations that apply to employers and physicians. Council wonders if it is appropriate that provisions such as these should neither be set out within the body of a regulation nor placed in a readily accessible official consolidation.

CONCLUSION

In previous advisory memoranda, council has observed that the development of occupational health regulations is a difficult and complex task, particularly in the context of an open consultative process. In the case of the proposed standard for noise, it is clear that the dialogue conducted between the ministry and members of the public has caused major changes to be made to the regulation and accompanying codes. Council is also highly appreciative of the open attitude taken by ministry officials in respect to the points raised by its Task Force on Regulations.

In reviewing the most recent version of the noise regulation, it is clear that a number of changes were made to the standard in the late stages of the regulatory process. Among the major changes put forward were a) the shift from a compliance strategy based on the calculation of average worker exposure to noise to an approach based on the measurement of instantaneous sound levels, and b) the exemption of highway vehicles from the application of the regulation. These changes came about as a result of submissions made to the ministry, and discussions that were held separately with labour and management representatives after the June 24, 1981 public meeting. In a letter to the former Minister of Labour, council has acknowledged that informal consultations may play a role in the development of occupational health standards. Council has indicated, however, that it is beyond the scope of its review function to comment on the non-public aspect of the consultative process. Although council still accepts this position, some members have questioned whether further public consultations might be desirable when what may be considered as major changes are made to a regulation as a result of discussions conducted after a public meeting. While council recognizes that the ministry has followed the normal consultative process for the development of occupational health regulations, it wishes to reiterate that any decision to expand this aspect of the process must ultimately rest with the minister.

Council members would point out the shift to a standard based on the measurement of sound levels represents a major change both in the substance of the regulation and in the philosophy for controlling excessive noise in the workplace. The result has been the creation of a more stringent noise regulation. Council understands, from the minister's letter of November 12, 1982, that the use of sound levels as the method for determining compliance with the regulation is intended to serve as an interim measure until the results of an independent study are received. Once these findings have been reviewed, the ministry may choose to adopt a different strategy, and base control limits on the average exposure of a worker to noise. The study will also investigate the appropriateness of the three and five-dB exchange rates and the economic costs associated with each. Council has suggested, elsewhere in this advisory memorandum, that such a study might be expanded to assess the economic feasibility of achieving an 85-dBA control level for the introduction of engineering controls. Should the ministry decide to amend the proposed regulation, either before or after the advice of the independent study group has been received, council presumes that the rationale for these changes will be set out when the standard is enacted.

In this advisory memorandum, council has also commented on other aspects of the analytical and legal-technical process. The most important points raised have concerned the absence in the proposed regulation of a) maximum exposure limits, b) a strategy to encourage manufacturers and designers to reduce noise levels in the machinery that they produce, and c) guidelines to help physicians determine when a worker suffering from hearing loss should be removed from a noise exposure environment.

To conclude, council members wish to acknowledge the considerable amount of work and care that ministry staff have put into the development of the proposed noise regulation. It is evident that the open consultative process pursued by the ministry and the response to public comment have contributed to the development of a strong regulation for the control of noise levels in the workplace.

Footnotes

1. Advisory Council on Occupational Health and Occupational Safety. Fourth Annual Report, April 1, 1981 to March 31, 1982. Toronto, p. 38.
2. Ontario Ministry of Labour, Occupational Health and Safety Division. The Report on the Designation of Noise in Ontario. Vol. 1, November 1982, p. F-38, F-52.
3. Advisory Council on Occupational Health and Occupational Safety. Second Annual Report, April 1, 1979 to March 31, 1980. Toronto, p. 92.
4. *Ibid*., p. 92.
5. British Health and Safety Commission. Protection of Hearing at Work, Contents of Proposed Regulations and Draft Approved Code of Practice and Guidance Notes. (London, England: Her Majesty's Stationary Office, 1980), pp. 11-12.
6. Advisory Council on Occupational Health and Occupational Safety. *Op. cit*., p. 94.
7. J. D. Royster and L. H. Royster. Evaluating the Effectiveness of Hearing Conservation Programs by Analysing Audiometric Data. Unpublished paper presented at The American Hearing Association Convention, Toronto, November 20, 1982.
8. U.S. Department of Labour, Occupational Safety and Health Administration. Occupational Noise Exposure; Hearing Conservation Amendment, 29 CFR, Part 1910, s. 95(d)(2).

APPENDIX I

Ontario

Office of the Minister

Ministry
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November 12, 1982

J. Fraser Mustard, M.D.,
Chairman,
Advisory Council on Occupational Health
and Occupational Safety,
15th Floor,
400 University Avenue,
Toronto, Ontario

Dear Dr. Mustard:

I am pleased to forward the proposed noise regulation to the Advisory Council for review and comments. The Ministry has reviewed the Council's advisory memorandum (79-III) on noise which has formed the basis for the proposed regulation.

The proposed regulation has the following features. It requires an assessment of workplaces in which workers are subject to a sound level of 80 dBA or above. A hearing conservation program is required (a) where a worker is subject to a sound level of 85 dBA for four or more hours a day or (b) where a worker is subject to a sound level of 90 dBA or more, regardless of the exposure time.

Employers are required to provide, and workers to wear, hearing protection when workers are subject to sound levels of 85 dBA or greater. Finally, subject to section 6 of the regulation, engineering controls are mandatory at sound levels of 90 dBA or more.

You will note that the regulation does not contain a provision for measuring average exposure to noise levels as did the regulation presented to the open review meeting on June 24, 1981. The reason for this is that following that meeting, the Ministry received a number or representations indicating that there is, within the scientific community, unresolved controversy concerning the appropriate averaging formula and more particularly, the numerical value to be used in the exchange rate.

Because of the different views expressed and because of our conclusion that there is an honest difference of view among scientists on this issue, we have decided to proceed with the regulation in the attached form, using sound levels rather than average exposures, as the basis for determining where remedial provisions will apply.

However, we are of the view that there is a need for an independent study as to the desirability of including in a regulation control limits based upon the average exposure of a worker to noise. The study should also address the question of what the appropriate exchange rate is and finally, assess the economic implications of whatever exchange rate may be deemed appropriate.

Within the next few weeks, we will be considering how best to undertake a study of the sort described above.

Yours sincerely,

for R. H. Ramsay,
Minister.

/attachment.

APPENDIX II

Agenda for Discussion

1. *The Action Level for the Introduction of Engineering Controls*

   The task force would like the ministry to elaborate on its rationale for increasing the action level for the introduction of engineering controls in the workplace from 85 to 90 decibels A-weighted (dBA). In particular, could the ministry state what evidence it relies on for the proposition that an 85-dBA level would be neither economically nor technologically feasible?

2. *Recent Studies on the Health Effects of Noise*

   The task force notes that the health effects document contained in the ministry's background materials is dated March 1, 1979. Members would like to know whether any important studies have been published recently that would alter the general conclusions set out in this document.

3. *The Absence in the Proposed Regulation of a Maximum Exposure Limit (MEL)*

   Could the ministry explain, for the benefit of task force members, why an MEL has not been specified in the proposed noise regulation?

4. *The Use of Sound Level Measurement as the Basis for Determining Compliance with the Proposed Regulation*

   The task force would like to explore, in greater depth, the ministry's rationale for shifting from a noise standard based on the calculation of average exposures to noise to one based on the measurement of sound levels.

5. *The Protection Which the Proposed Regulation Affords to Employees on Extended Work Shifts*

   Could the ministry express its views on the question of whether a regulation based on the measurement of sound levels will provide adequate protection to employees who are required to work 10 or twelve-hour shifts?

6. *The Employer's Obligation to Protect the Hearing of Non-Employees*

   Pursuant to sub-section 4(2) of the proposed noise regulation, an employer's obligation to protect the hearing of a non-employee will arise when two pre-conditions are fulfilled: a) the non-employee must be subjected to noise at the employer's worksite, and b) the health of the non-employee must be affected thereby. The task force wishes to note that under sub-section 12(1) of the proposed noise regulation, the implementation of a hearing conservation program is not made dependant on a finding that the health of workers will be affected by noise. Rather, such a program must automatically be established where sound levels exceed certain levels. On the basis that 'effect on health' is not a prerequisite for introducing a hearing conservation program, the task force would like to hear discussion on why this factor should be relevant in defining an employer's obligation towards non-employees.

7. *The Exclusion of Truck Drivers (and the Drivers of Other Vehicles) from the Ambit of the Proposed Regulation*

Sub-section 4(3) of the proposed noise regulation specifies that workers in or on vehicles (as defined under the *Highway Traffic Act*) operated on highways (as defined under the *Highway Traffic Act*) and their employers will be exempted from the provisions contained in the noise regulation. The task force would like to discuss with ministry officials the rationale for this exclusion and, more particularly, the basis for the ministry's belief that it would be more appropriate to develop a separate noise regulation for truck drivers.

The task force also has a concern that the definitions accorded to the terms 'vehicle' and 'highway' could cause confusion when the regulation is administered in the field. For example, while a truck driver loading supplies in an industrial site would be covered by the noise regulation, the regulation would cease to apply as soon as the vehicle entered a public highway. The task force wonders if the ministry has considered the potential problems that could arise as a result of the definitions chosen. Furthermore, could the ministry explain why the proposed noise regulation does not actually spell out the definitions contained in the *Highway Traffic Act*?

8. *Duties Placed on the Designers and Manufacturers of Equipment*

Pursuant to section 7 of the proposed regulation on hearing protection developed by the British Health and Safety Commission, a number of specific duties, relative to the control of noise, are specified for organizations that either design, manufacture, import or supply equipment and machinery for use in the workplace. These obligations include: a) a broad duty to ensure, as far as is reasonably practicable, that an article does not produce noise likely to be injurious to hearing, and b) (where high levels of noise cannot be engineered out) a requirement that adequate information be provided to users on the noise levels likely to be produced by the article, and the steps that should be taken to minimize exposures. The task force would like to obtain the ministry's view on whether similar provisions should be incorporated into the proposed noise regulation.

9. *The Duty Placed on Employers to Reduce Sound Levels to the Lowest Practical Level through the Use of Engineering Controls*

Under sub-section 5(1) of the proposed noise regulation, an employer (whose workers are subjected to sound levels greater than or equal to 90 dBA) is required to adopt engineering controls to reduce sound levels in a workplace to the lowest practical level below 90 dBA. The employer's duty under this sub-section is a continuing one. That is to say, even though the employer, through the successful application of engineering controls, is able to reduce sound levels below the 90-dBA action level (for example to 86 dBA) he or she will still be obliged to attenuate noise further, until the lowest practical level has been attained. The task force wishes to note, however, that an employer whose workers are subjected to sound levels just below 90 dBA (for arguments sake, 89 dBA) is not required to adopt any measures by way of engineering controls to reduce the levels of sound in the workplace. The task force would like to discuss with ministry officials the question of whether it is equitable to impose different types of obligations on the two classes of employers that are based solely on the levels of sound that were *originally* measured in a workplace.

10. *The Statutory Defence Available to the Employer under Sub-section 5(2) of the Proposed Noise Regulation*

Sub-section 5(2) of the proposed noise regulation states that 'on a prosecution for a failure to comply with s.5(1) [the sub-section that specifies a 90-dBA action level for the introduction of engineering controls], it shall be a defence for an employer to prove that he has complied with s.5(1) and that the breach of s.5(1) occurred solely because a worker failed to work in compliance with the work practices specified in a hearing conservation program under s.12(2)'. The task force wishes to note that, under the provisions of the five designated substances regulations promulgated to date, an employer may not avail himself of this type of statutory defence unless he can also prove that every precaution reasonable in the circumstances was taken to require the worker to comply. Could the ministry explain why this additional provision has not been incorporated into the proposed noise regulation?

11. *Action to be Taken when a Further Assessment Reveals a Significant Decrease in the Levels of Noise Recorded in a Worksite*

The task force would like to discuss the following point with ministry officials. Where a further assessment conducted pursuant to section 13 of the proposed noise regulation discloses that noise levels no longer exceed a) 85 dBA or more for a period of four or more hours in a working day, and b) 90 dBA for any period of time, will an employer be entitled to dismantle a hearing conservation program that already exists or will he continue to be bound by the general duty, contained in section 2 of the regulation, to reduce noise to the lowest practical level?

12. *Fitness for Exposure to Noise*

Could the ministry explain, for the benefit of task force members, why the Code for Medical Surveillance of Noise-Exposed Workers does not contain guidelines to help plant physicians determine when a worker will be considered 'unfit' or 'fit with limitations' for work in a noise exposure environment?

13. *An Employee's Entitlement to Workers' Compensation Benefits*

The task force has a concern that sub-section 20(2) of the proposed noise regulation may convey to workers the false impression that noise-induced hearing loss is compensable, whether or not the condition arises as a result of occupational exposures. In this respect, task force members wonder whether the phrase 'exposure to noise' on the third line of the sub-section should not be amended to read 'occupational exposure to noise'.

14. *The Code for Medical Surveillance of Noise-Exposed Workers*

The task force would also like to discuss several points that relate to the Code for Medical Surveillance of Noise- Exposed Workers. Members wish to focus first on sub-section 3(3)(b) of the code and, in particular, on the sentence which states that 'workers with a confirmed hearing loss of 25-dB average at 0.5, 1, 2 and 3 kHz in both ears should be referred for Workers' Compensation Board (WCB) assessment, if the hearing loss is thought to be occupationally induced.' Could the ministry explain, for the benefit of task force members:

a) The intended purpose of the WCB assessment specified in this sub-section (i.e. is the assessment designed to determine eligibility for compensation or to provide a method by which a plant physician can confirm a diagnostic finding)?
b) The rationale for not making a referral mandatory when a worker experiences a 25-dB average hearing loss over the four specified frequencies.
c) The reasons for specifying that a 25-dB average hearing loss must be recorded in *both* ears (rather than in either ear as stated in an earlier version of the code) before a referral can take place.
d) The rationale for requiring that the WCB assessment be conducted only where a plant physician considers that a worker's hearing loss has been occupationally induced—when this is precisely the issue that the WCB must resolve.

Task force members would also like to obtain the ministry's views on why plant physicians should not be required to provide joint health and safety committees with annual reports that summarize the results of audiometric tests conducted on workers.

15. *Return to Work*

Under sub-section 4(1) of the Code for Medical Surveillance for Vinyl Chloride, it is stated that a decision shall be made by a physician in respect to when a worker previously removed from a vinyl chloride environment may be permitted to return to work. The task force would be interested in knowing why a similar sort of provision has not been included in the medical surveillance code for noise.

16. *The Definition of a 'Significant Threshold Shift'*

Sub-section 7(2) of the Code for Audiometry of Noise-Exposed Workers defines a significant threshold shift as a difference of 15 dB at 3,000 or 4,000 Hz compared with either the baseline or previous audiogram. Could the ministry elaborate on its reasons for a) selecting 15 dB as the measure of significant threshold shift, and b) specifying that only two speech frequencies must be considered when threshold shift is measured?

17. *The Nature and Extent of the Consultative Process Entered into After the June 24, 1981 Public Meeting*

The task force wishes to note that the ministry's decisions to adopt a regulatory strategy based on area monitoring and to exempt truck drivers from the application of the regulation were not discussed at the June 24, 1981 public meeting. Could ministry officials therefore elaborate on the steps taken to obtain public input in respect to these changes?

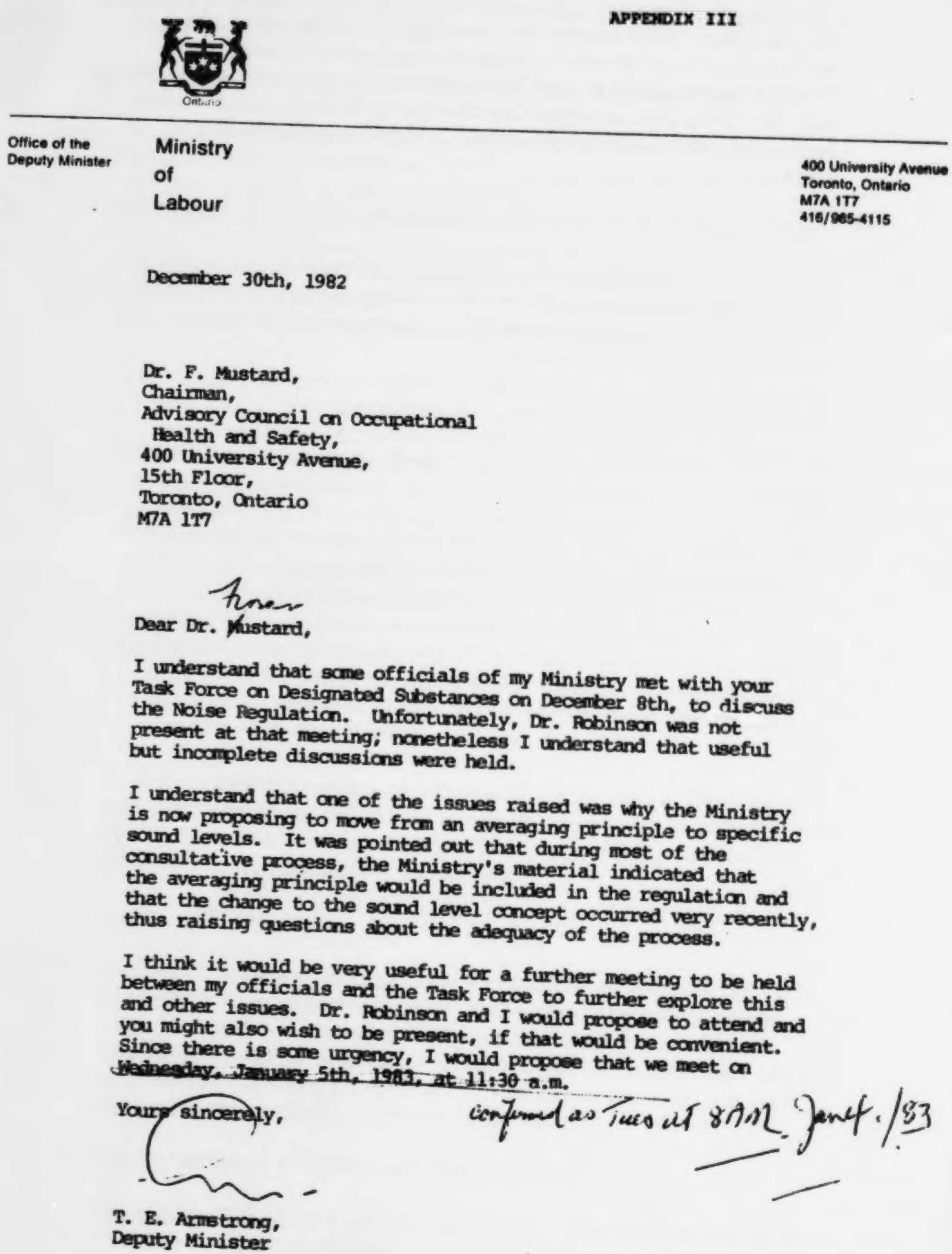
18. *The Publication of Codes in the Official Consolidation of Regulations*

The task force would like to know whether it is the intention of the ministry to have the codes that are annexed to the proposed noise regulation (and to other designated substances regulations) published in the official consolidation of regulations.

19. *Some Miscellaneous Points*

Task force members would like the ministry to consider the following points:

a) Is the phrase 'and in any case the level be reduced to' contained in the last two lines of sub-section 5(1) superfluous?
b) What is meant by the term 'sound level of noise'?



APPENDIX III

Ontario

Office of the
Deputy Minister

Ministry
of
Labour

400 University Avenue
Toronto, Ontario
M7A 1T7
416/965-4115

December 30th, 1982

Dr. F. Mustard,
Chairman,
Advisory Council on Occupational
Health and Safety,
400 University Avenue,
15th Floor,
Toronto, Ontario
M7A 1T7

Fraser

Dear Dr. ~~Mustard~~,

I understand that some officials of my Ministry met with your Task Force on Designated Substances on December 8th, to discuss the Noise Regulation. Unfortunately, Dr. Robinson was not present at that meeting; nonetheless I understand that useful but incomplete discussions were held.

I understand that one of the issues raised was why the Ministry is now proposing to move from an averaging principle to specific sound levels. It was pointed out that during most of the consultative process, the Ministry's material indicated that the averaging principle would be included in the regulation and that the change to the sound level concept occurred very recently, thus raising questions about the adequacy of the process.

I think it would be very useful for a further meeting to be held between my officials and the Task Force to further explore this and other issues. Dr. Robinson and I would propose to attend and you might also wish to be present, if that would be convenient. Since there is some urgency, I would propose that we meet on ~~Wednesday, January 5th, 1983, at 11:30~~ a.m.

Yours sincerely,

confirmed as Tues at 8AM. Jan 4./83

T. E. Armstrong,
Deputy Minister

Ontario

Office of the Minister

Ministry
of
Labour

400 University Avenue
Toronto, Ontario
M7A 1T7
(416) 965-4101

March 8, 1983

J. Fraser Mustard, M.D.,
Chairman,
Advisory Council on Occupational
Health and Occupational Safety
15th Floor
400 University Avenue
Toronto, Ontario

Dear Dr. Mustard:

Thank you for your letter of January 21, 1983, enclosing the Council's Advisory Memorandum 82-IV concerning the proposed noise regulation. The memorandum contains a comprehensive review of the regulation and I appreciate the effort that went into preparing this important document.

The principal issue of concern relates to the exposure value, above which engineering controls are required. This letter deals only with that issue. The other matters raised in Council's memorandum will be dealt with in a separate response, which I expect to be able to send to you shortly.

I noted in my letter of transmittal, dated November 12, 1982, that the proposed regulation did not contain a provision for measuring a worker's average exposure to noise as did the regulation presented to the public on June 24, 1981. I also pointed out that there is, within the scientific community, unresolved controversy concerning the appropriate averaging formula. Accordingly, the Ministry proposed to proceed with a regulation based on a sound level concept, and to set up a task force to consider the appropriate formula for computing average exposure over an appropriate time period.

Following the submission of the proposed regulation to Council, my officials met with members of Council task force to review the reasons for this change. These reasons are set out in detail in the Advisory Memorandum. The memorandum indicates that some Council members believed that this change to the regulation had received insufficient comment and review by the interested parties and, indeed, that the parties were denied the opportunity for fair comment. Other Council members believed that the degree of public comment and participation that had taken place met the requirements of a fair consultative process.

The Ministry has developed an open and, I believe fair consultative process for developing designated substance regulations. The Ministry is now faced with the dilemma whether to proceed with an interim regulation, recognising that the exchange rate issue remains unresolved, or whether to wait to have this issue resolved expeditiously by means of a task force, with focussed terms of reference and a reasonably short but practical reporting deadline. After careful reflection I have decided to adopt the latter course of action with the intention of having the final regulation in place this summer.

Accordingly, I have appointed a three man advisory committee. The chairman is Mr. Kevin Burkett, who chaired the Federal-Provincial Inquiry into Mine Safety and who is now the Alternate Chairman of the Labour Relations Board. Mr. Norman Lockington of Dofasco and Mr. Ken Valentine of the United Steelworkers of America are the other members. Dr. Edgar Shaw, head of the Acoustics Section of the National Research Council will act as the committee's technical advisor. A copy of the terms of reference of the committee is attached for your information.

Pursuant to the Advisory Council's advice concerning the need for further consultation with the parties, the Special Committee will invite representations from management and labour on the items noted in the terms of reference. I am advised that the Committee will place advertisements in the daily papers of Ontario, calling for the submission of written briefs by April 15, 1983. The Committee will also invite comment from experts in the field and individuals who have submitted briefs to the Ministry on the noise regulation. The Committee may meet with the parties concerned to seek clarification or elaboration of their briefs. Prior to reporting to me, the Committee will circulate draft proposals for comment to those who have submitted briefs.

Through this consultative process, I am confident that the parties will be provided with ample opportunity to present their views on the remaining outstanding issues concerning the noise regulation.

I have asked the committee to report to me by July 1, 1983. In the meantime, I would draw Council's attention to the fact that workers in industrial establishments are protected by the provisions of section 144 of the Regulations for Industrial Establishments.

Yours sincerely

R. H. Ramsay
Minister

Attachment

Terms of Reference Special Advisory Committee on the Noise Regulation

Preamble

Following extensive consultation with representatives of management and labour and in consideration of the advice provided by the Advisory Council on Occupational Health and Occupational Safety, the Ministry of Labour has determined that a noise regulation will contain the following provisions:

1. The measurement of noise at and above 80 decibels;
2. the requirement upon employers to reduce noise at the work place to 90 decibels on a time weighted average basis by means of engineering controls, and in any case to the lowest level practical;
3. the mandatory use of hearing protection where a worker is exposed to noise that cannot be reduced to 90 decibels on a time weighted average basis, or where a worker is exposed to 85 decibels for 4 or more hours during a work day; and
4. the requirement upon employers to establish a hearing conservation program where a worker is exposed to 90 decibels or more on a time weighted average basis or to 85 decibels for 4 or more hours during a work day.

The Ministry has not determined either the method for calculating the average level of exposure and what time frame or time frames should be used to calculate the average level of exposure for purposes of framing regulations in respect of engineering controls (para. 2 above), mandatory hearing protection (para. 3 above) and mandatory hearing conservation programs (para. 4 above). In addition, the Ministry has not determined whether noise ceiling levels should be imposed taking into account the nature of the sound and the attenuation provided by hearing protection. These issues give rise to complex scientific and social considerations. Accordingly, a committee has been established to study these issues and report to the Minister. The terms of reference of the special Advisory Committee on the Noise Regulation are set out below.

Terms of Reference

1. To evaluate the available scientific information on the exchange rate to be used in an Ontario noise regulation.

2. To evaluate the available scientific information with respect to whether there should be different time frames used to calculate the average level of exposure for purposes of engineering controls, mandatory hearing protection and mandatory hearing conservation programs.

3. To evaluate the available scientific information on the manner in which impulse noise ought to be treated in the regulation.

4. To evaluate the available scientific information on the need for ceiling levels in the noise regulation, taking into account the nature of the

sound and the attenuation provided by ear muffs and other similar personal protective devices.

5. To consult with interested parties on the scientific matters listed above and to include consideration of the social and economic implications of these matters.

6. To report and make recommendations on the above items to the Minister no later than July 1, 1983.

Ontario

Advisory Council on
Occupational Health &
Occupational Safety

Office
of the
Chairman

400 University Avenue
Toronto, Ontario
M7A 1T7

416/965-2448

March 11, 1983

The Honourable R. H. Ramsay
Minister of Labour
400 University Avenue, 14th Floor
TORONTO, Ontario

Dear Mr. Minister:

Thank you for your letter of March 8, 1983 in connection with council's Advisory Memorandum 82-IV on the proposed noise regulation.

You refer in your letter to the changes which were made since the June 24, 1981 regulation which had contained a provision for measuring a worker's average exposure to noise. You quite rightly point out that, whereas some council members believed that this change to the regulation had received insufficient comment and review by the interested parties, others believed that the degree of public comment and participation that had taken place met the requirements of a fair consultative process.

On page two of the letter it is stated that the Special Committee will invite representations from management and labour, "pursuant to the advisory council's advice concerning the need for further consultation with the parties ...". So as to avoid any misinterpretation, it is important to point out that, because there were divergent views among members, council did not offer any advice on this point. Indeed, in its concluding comment on the subject of further public consultations, council noted that the ministry had followed the normal consultative process for the development of occupational health regulations, and that any decision to expand this aspect of the process must ultimately rest with the minister.

Yours truly,

J. F. Mustard, M.D.
Chairman

cc to: T. E. Armstrong, Q.C.
Dr. A. E. Robinson

Advisory Memorandum 82-V

Ontario

Advisory Council on
Occupational Health &
Occupational Safety

Office
of the
Chairman

400 University Avenue
Toronto, Ontario
M7A 1T7
416/965-2448

February 14, 1983.

The Honourable Russell H. Ramsay,
Minister of Labour,
400 University Avenue,
14th Floor,
Toronto, Ontario.
M7A 1T7

Dear Mr. Minister:

On behalf of the advisory council, I am pleased to submit Advisory Memorandum 82-V on "Principles and Procedures for the Interpretation of Epidemiological Studies". A detailed appendix which accompanies this document will be forwarded shortly.

This advisory memorandum is the first of a series of documents which council plans to prepare on the subjects of the interpretation of health effects data and the role of economic analysis in the standard-setting process.

Council hopes that the enclosed advice will be helpful.

Yours truly,

J. F. Mustard, M.D.
Chairman

Encl.

c.c. T. E. Armstrong, Q.C.
Dr. A. E. Robinson

Advisory Memorandum 82-V
to the Minister of Labour
February 14, 1983

Principles and Procedures for the Interpretation of Epidemiological Studies

INTRODUCTION

In the formulation of regulatory strategies for the control of occupational health hazards, a key issue is the adequacy of the information base for decision-making purposes. Since data on the health effects associated with exposure to workplace agents are often imperfect, it is essential that policy makers develop the skills to evaluate health studies in a critical fashion. The advisory council believes that the difficult task of regulating occupational health hazards could be facilitated if a standardized approach were adopted in respect to the analysis and interpretion of health effects data. The approach would involve the articulation of a series of guidelines that regulators could employ to gauge the inherent quality of individual studies. In council's view, the framework developed should address the following points:

a) Principles and procedures to assess the general quality of research papers based on an analysis of their study design.
b) Criteria to judge the strengths and weaknesses of individual studies that fall within particular design categories according to accepted methodological frameworks.
c) Rules to determine whether associations revealed in health effects studies (i.e. between environmental factors and subsequent disease outcomes) are causal in nature.

The advisory council believes that the development of frameworks through which health effects studies can be evaluated will produce a number of concrete benefits. First, the process by which different studies are interpreted, classified and ranked will be facilitated. As a result, it will be easier for policy makers to identify studies that possess high inherent quality, and which should be employed in the standard setting process. Second, the promulgation of such frameworks will enable interested parties to comprehend more fully the manner in which regulators interpret and weigh the results of individual studies. With this knowledge in hand, labour and management groups would be better able to structure their submissions to government on the merits of particular health effects studies. A more effective interchange of views between government and interested parties would, thus, be anticipated. Third, the provision of an interpretative framework would assist review bodies, such as the Advisory Council on Occupational Health and Occupational Safety, to determine whether health studies have been evaluated in a proper fashion. Finally, the frameworks could be employed by compensation boards to help determine whether a causal relationship exists between a workplace agent and a disease outcome so as to make the disease compensable.

Principles and Procedures for the Interpretation of Epidemiological Studies

In developing strategies for the control of hazardous agents in the workplace, the first step is to review the relevant scientific literature. Ordinarily, two broad classes of studies will be of interest to researchers. These categories are epidemiological studies and animal bio-assays. Epidemiological studies, which will be considered in the present advisory memorandum, may be defined as research projects which endeavour to assess the distribution of diseases in human populations, and the causes or determinants of these diseases.

Epidemiology cannot be characterized as an exact science. That is the case because a particular type of disease is rarely caused by one factor acting independently. Rather, most diseases are brought about by the interplay of many contributing factors whose individual impacts may be difficult to assess. One cannot, therefore, realistically expect that epidemiological studies will be able to gauge, in a precise fashion, the extent to which different factors have caused a particular disease. Epidemiological studies, however, do provide useful information with respect to whether an individual agent may have contributed to the development of a disease under investigation.

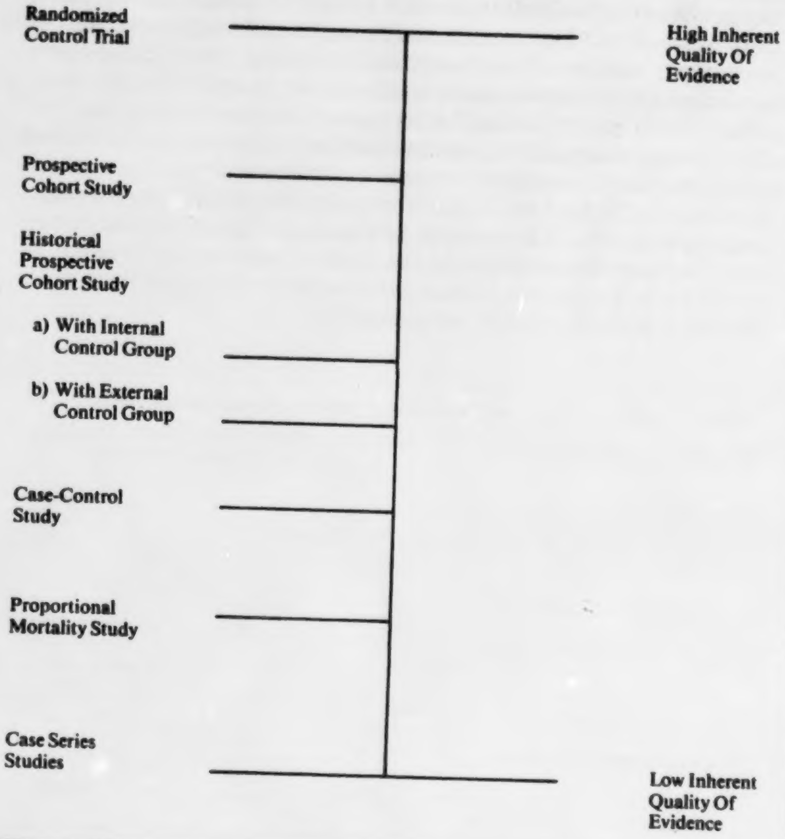
Occupational epidemiology studies (i.e. epidemiological studies conducted on workplace populations) may be divided into two general categories—mortality studies and morbidity studies. Mortality studies are designed to examine the effects that particular environmental factors have on the incidence and pattern of deaths among workers. Morbidity studies, on the other hand, seek to investigate the relationship between environmental factors and the incidence of disease in work force populations. Although common criteria can be employed to assess various aspects of both study categories (e.g. the adequacy of exposure records), other aspects of the analysis will require separate methodological assessment.

a) *Occupational Mortality Studies*

There are six different study designs that could be employed to conduct research on the incidence of mortality in the workplace. These designs, which are set out in Figure 1, typically produce results of a fixed inherent quality. The appendix, which is attached to this document, provides a full description of each study design, assesses the strengths and weaknesses of each approach, and provides criteria from which to evaluate the quality of individual research papers that fall within a specific design category. It should be noted, at this stage, that approximately 95 per cent of all occupational mortality studies follow either the historical prospective cohort or proportional mortality design. As a result, the appendix will place extra emphasis on a discussion of these two study types.

In Figure 1, the advisory council has also set out a scale for ranking the quality of evidence obtained from different classes of occupational mortality study designs. As can be seen from the diagram, the evidence obtained from a randomized control trial is considered to possess the highest level of inherent quality. As one moves to less stringent study designs, however, the quality of the results obtained tends to diminish.

Figure 1: **The Quality of Evidence Typically Associated with Different Classes of Occupational Mortality Study Designs**


Randomized Control Trial
High Inherent Quality Of Evidence
Prospective Cohort Study
Historical Prospective Cohort Study
a) With Internal Control Group
b) With External Control Group
Case-Control Study
Proportional Mortality Study
Case Series Studies
Low Inherent Quality Of Evidence

According to accepted epidemiological practice, a research paper that falls into a design category on the high end of the scale will almost always be preferred to a study whose design category appears closer to the bottom of the ranking. There may exist situations, however, where a study with a strong design may be so flawed in some respects that it ought not to be used as a basis for setting occupational health standards. If this is the case, then another study with an inferior design might be the only source available from which one could draw an association between exposure to a particular agent and a health risk.

Although study designs at the low end of the scale suffer from major deficiencies in design, the observations culled from these research materials often provide useful first stage assessments of the adverse health effects that could be produced by an environmental agent. As an example, case series studies provided the first suggestive evidence that angiosarcoma of the liver was caused by occupational exposure to vinyl chloride. When the results of a study with a low ranking design indicate that a particular agent may pose a threat to worker health, the next step could involve i) initiating immediate regulatory action and/or ii) undertaking more sophisticated epidemiological studies.

In addition to specifying guidelines for the ranking of different categories of occupational mortality studies according to their design, there is also a need to set out criteria that regulators might employ to evaluate the quality of individual studies that fall within the same generic category. Frameworks for assessing the strengths and weaknesses of various study types have been described in the literature.[1] The advisory council has drawn on these materials in an attempt to develop a comprehensive set of criteria for evaluating the two most common classes of study designs encountered in the occupational mortality field (i.e. historical prospective cohort and proportional mortality studies). These criteria are set out in Tables 1 and 2, and are analysed in detail in the accompanying appendix. A framework for the evaluation of the case control study (a design that is useful for the study of rare diseases) will not be set out since this approach tends to be employed infrequently in the context of occupational epidemiology.[2]

Table 1: Criteria For Evaluating The Quality of Historical Prospective Cohort Studies

1) **Definition of the Study Cohort**
    - a) Method of Selection
    - b) Criteria for Inclusion or Exclusion
    - c) Extent to Which All Cohort Members Were Considered
    - d) Size of the Cohort

2) **Quantification of Exposure**
    - a) Detail in Work History Files
    - b) Extent of Industrial Hygiene Data
    - c) Quality of Industrial Hygiene Data
    - d) Consideration of Confounding Factors

3) **Ascertainment of Mortality**
    - a) Quality of Follow-up Technique
    - b) Completeness of Follow-up
    - c) Availability of Death Certificates or Other Records to Determine the Cause of Death
    - d) Length of Follow-up

4) **Analysis of Results**
    - a) Suitability of the External Control Group
    - b) Availability of an Internal Control Group
    - c) Allowance for Latency Effects
    - d) Use of Appropriate Statistics
    - e) Demonstration of an Exposure Gradient
    - f) Discussion of Possible Biases

Table 2: Criteria For Evaluating The Quality of Proportional Mortality Studies

1) Extent to Which All Deaths in the Study Group Have Been Recorded.

2) Method by Which Deaths Are Classified.

3) The Basis for Choosing a Control Group.

4) Classification of Mortality Data by Age and Calendar Time of Death.

5) Elimination of Obvious Competing Risks.

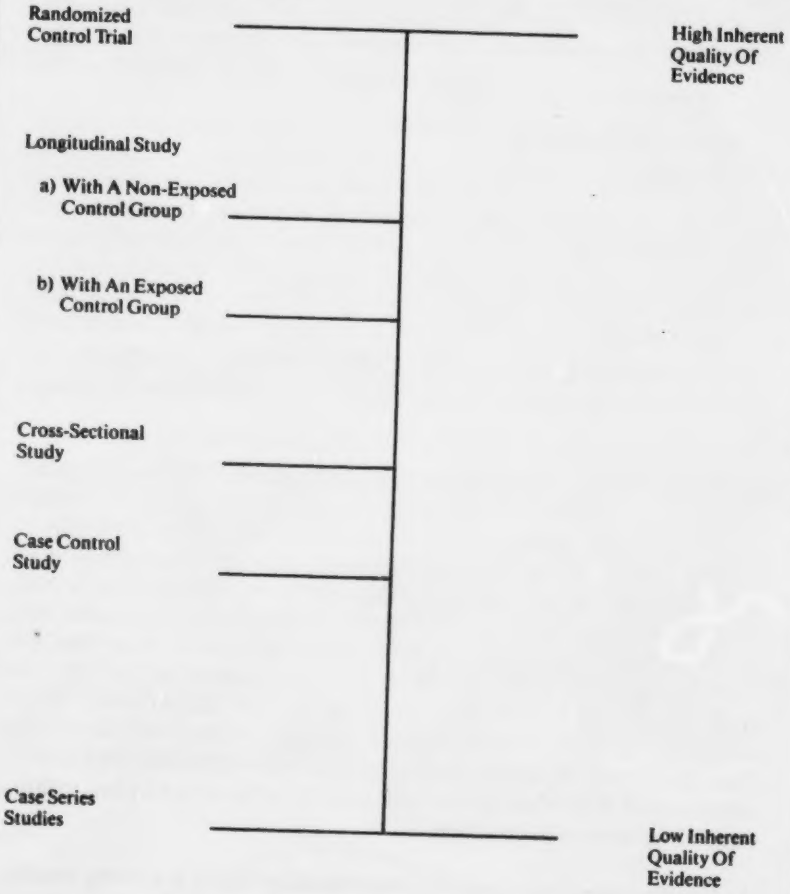
6) Illustration of an Exposure Gradient.

7) Allowance for Latency Effects.

b) *Occupational Morbidity Studies*

There are essentially five study designs that may be utilized to conduct research on disease outcomes in the workplace. Each of these designs typically produces evidence of a fixed inherent quality. The rules for ranking occupational morbity studies are similar to those that have already been set out for occupational mortality studies. As indicated in Figure 2, evidence obtained from a randomized control trial is judged to have the highest degree of quality, and may be used with confidence in drawing associations between environmental agents and workplace disease. It will also be seen that the quality of evidence decreases as one moves to weaker study designs. The appendix, which is attached to this document, will discuss the attributes of each study design.

Figure 2: The Quality of Evidence Typically Associated with Different Classes of Occupational Morbidity Study Designs


Randomized Control Trial
High Inherent Quality Of Evidence
Longitudinal Study
a) With A Non-Exposed Control Group
b) With An Exposed Control Group
Cross-Sectional Study
Case Control Study
Case Series Studies
Low Inherent Quality Of Evidence

As in the case of mortality studies, there is a need to establish criteria for the evaluation of morbidity studies that fall within particular design categories. In Table 3, the advisory council has drawn together a list of evaluative criteria, which, it believes, should be considered in assessing the quality of individual morbidity studies. These criteria are general in nature and may be applied to randomized control trials, longitudinal studies and cross-sectional studies. A separate framework for the evaluation of case-control studies has not been included since this class of design is not ordinarily encountered in the occupational morbidity field.

Table 3: Criteria for Evaluating The Quality of Occupational Morbidity Studies

a) The Provision of an Inception Cohort.

b) The Clinical Validity of the Outcome Investigated.

c) The Reliability of the Measure of Outcome.

d) Strategy Taken to Ensure a Blind Assessment of Outcome.

e) The Extent to Which All Cohort Members Were Recruited.

f) Criteria for Inclusion/Exclusion.

g) The Length of the Follow-up Period.

h) The Basis for Comparison.

i) Other Criteria Broadly Applicable to All Classes of Epidemiological Studies.

c) *Should a Scoring Mechanism Be Developed to Assess the Quality of Mortality and Morbidity Studies that Fall Within a Particular Design Category?*

In its deliberations, the advisory council considered the question of whether some scoring system could be developed to gauge the extent to which individual studies were able to fulfil the specified evaluative criteria. One of the approaches discussed involved the adoption of a three step procedure for assessing the quality of a study.[3] First, a numerical score would be assigned to each criterion, based on its relative importance. Next, guidelines would be established to ascertain when a criterion had been wholly satisfied, partially fulfilled, or not addressed at all. Finally, the scores obtained for each of the criteria would be added up, and the study with the highest cumulative score would be judged most persuasive. A less detailed approach would dispense with the allotment of individual scores and would simply assign a plus, minus or neutral value to each criterion.[4]

Although council members felt that the adoption of a scoring mechanism could be useful in those circumstances where regulators must extract the best evidence from a variety of similar epidemiological studies, it was concluded that the difficulties engendered by such an approach might outweigh the benefits obtained. For example, it might not be possible to obtain a consensus on the weight that should be accorded to different evaluative criteria. Second, even if a weighting scheme were agreed upon, there would inevitably exist disagreement on the degree to which an individual criterion had been satisfied. Finally, the adoption of a scoring system could lend to an evaluative framework a degree of analytical precision that might not be justified. For these reasons, and on the basis that a scoring system is not, strictly speaking, essential for the evaluation of health effects studies, the advisory council has not recommended that such a mechanism be adopted as a matter of general practice. Council wishes to note, however, that a scoring system might prove useful in some situations.

d) *Criteria for Determining Whether the Associations Revealed in Epidemiological Studies are Causal in Nature*

In determining what degree of weight should be placed on the evidence obtained from an epidemiological study, it is necessary to distinguish between the concepts of association and causation. Two variables (e.g. exposure to agent (X) and the incidence of disease (Y)) are said to be associated when they are related to one another in some fashion. A causal relationship arises, on the other hand, when the disease is shown to be induced by the environmental agent.

Since the scientific literature is replete with reports linking environmental agents to disease outcomes, there is a need to develop guidelines to help ascertain whether the relationships identified in reports are, indeed, causal in nature. One such framework, originally conceived by Sir Austin Bradford Hill[5] and later refined by Dr. David Sackett,[6] is particularly suitable for this purpose. The framework, which is set out in Table 4, consists of nine diagnostic tests for causation that can be applied to all classes of occupational mortality and morbidity studies. The tests are ranked in decreasing order of importance and are described fully in the appendix.

It should be emphasized that there is no single diagnostic test whose results will necessarily prove or disprove causation. Rather, the demonstration of a cause and effect relationship will depend on an evaluation of all nine criteria. In addition, the first five diagnostic tests listed in Table 4 are considerably more important than the last four, for the purpose of establishing causation. It must also be appreciated that, on some occasions, the listed criteria will not be able to provide useful information on the question of whether or not a causal relationship exists. In this respect, it would be desirable for regulators to establish clear principles for drawing inferences from data that are incomplete or otherwise inadequate. This issue will be addressed in detail in a subsequent advisory memorandum.

Table 4: A Framework for Determining Whether an Association Revealed in a Study is Causal in Nature

(NOTE: Tests Are Ranked in Decreasing Order of Importance)

1) Does There Exist Evidence on the Subject from True Experiments in Humans (i.e. from Randomized Control Trials)?

2) Is the Association Strong?

3) Is the Association Consistent from Study to Study?

4) Is the Temporal Relationship Correct?

5) Is There a Dose-Response Gradient?

6) Does the Association Make Epidemiologic Sense?

7) Does the Association Make Biologic Sense?

8) Is the Association Specific?

9) Is the Association Analogous to a Previously Proven Causal Relationship?

(Adapted from D. Sackett, *A Review of Diagnostic Tests for Causation,* Paper Prepared for the Ontario Royal Commission on Asbestos, Dec. 12, 1980.)

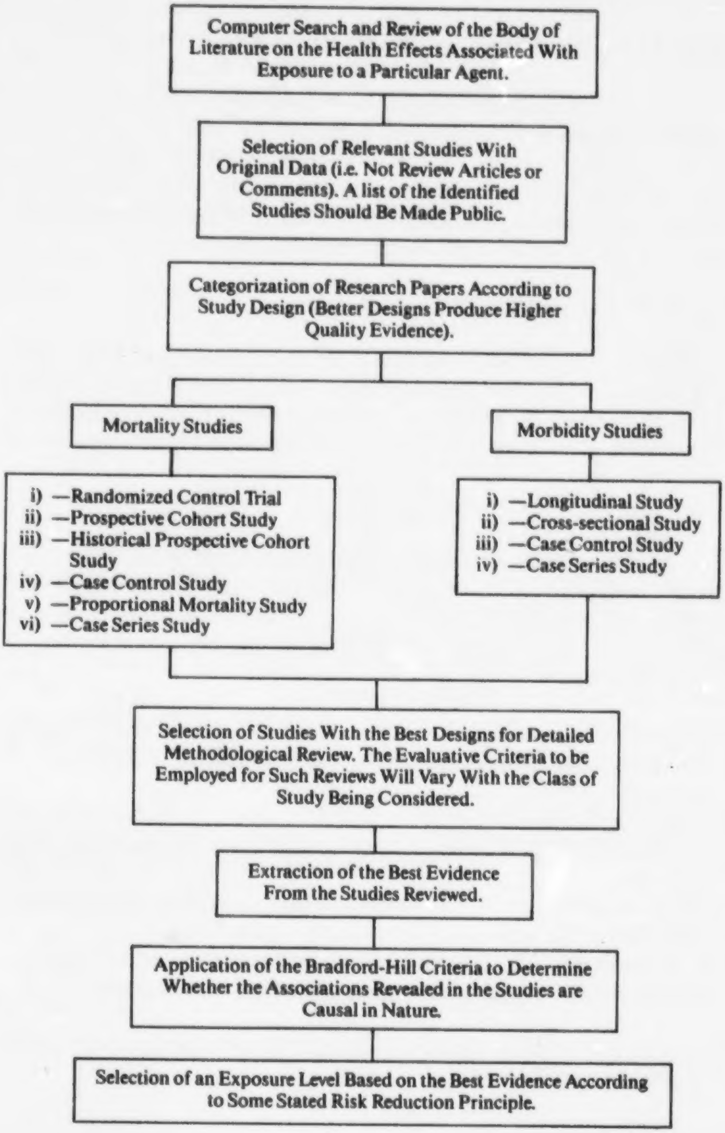
e) *A Recommended Process for the Interpretation of Epidemiological Studies*

The advisory council has, in Figure 3, illustrated a process that, it believes, should be followed to identify the best evidence obtained from epidemiological studies. While council appreciates that the Ministry of Labour may either explicitly or implicitly follow these steps in the development of occupational health regulations, members, nonetheless, feel that a standardized approach towards the evaluation of epidemiological studies would bring into sharper focus the criteria utilized by the ministry to rank competing research papers.

The publication of such criteria should also contribute to a heightened awareness among members of the public with respect to how one distinguishes between studies that are methodologically sound and those that exhibit serious deficiencies in design. It is council's view that the rules for interpreting and ranking epidemiological studies are generally not well known outside the epidemiological community. As a result, discussions on the scientific basis for setting occupational health standards have tended not to focus on the quality of evidence issue. It is hoped that the evaluative frameworks promulgated in this advisory memorandum will help to enhance the general quality and clarity of the debate between regulators and members of the public.

It should be noted that the frameworks advanced are not intended to serve as tight and inflexible analytical models. Rather, it is contemplated that the criteria that have been outlined will serve as grids against which the attributes of particular studies can be assessed. The applicability of any framework will depend on the nature of the available information base.

Figure 3: A Recommended Process to be Followed to Assess The Quality of Epidemiological Studies and to Establish Control Levels Based on The Evidence Obtained


Computer Search and Review of the Body of Literature on the Health Effects Associated With Exposure to a Particular Agent.
Selection of Relevant Studies With Original Data (i.e. Not Review Articles or Comments). A list of the Identified Studies Should Be Made Public.
Categorization of Research Papers According to Study Design (Better Designs Produce Higher Quality Evidence).
Mortality Studies
Morbidity Studies
i) —Randomized Control Trial
ii) —Prospective Cohort Study
iii) —Historical Prospective Cohort Study
iv) —Case Control Study
v) —Proportional Mortality Study
vi) —Case Series Study
i) —Longitudinal Study
ii) —Cross-sectional Study
iii) —Case Control Study
iv) —Case Series Study
Selection of Studies With the Best Designs for Detailed Methodological Review. The Evaluative Criteria to be Employed for Such Reviews Will Vary With the Class of Study Being Considered.
Extraction of the Best Evidence From the Studies Reviewed.
Application of the Bradford-Hill Criteria to Determine Whether the Associations Revealed in the Studies are Causal in Nature.
Selection of an Exposure Level Based on the Best Evidence According to Some Stated Risk Reduction Principle.

ACOHOS RECOMMENDATION 82-1

that the Ministry of Labour develop and publicize frameworks similar to the ones outlined in this advisory memorandum for the evaluation of different classes of epidemiological studies.

ACOHOS RECOMMENDATION 82-2

that the Ministry of Labour modify the format of the background materials that accompany each designated substances regulation to have these materials contain a summary list of the major epidemiological studies ranked according to overall methodological quality, which the ministry has relied upon to set control levels for the agent being regulated. Such rankings should be based on defined evaluative frameworks.

ACOHOS RECOMMENDATION 82-3

that in those situations where an agent designated for regulation produces a number of adverse health effects, the ministry consider the option of a) classifying the studies according to the outcomes of interest, and b) ranking the studies within each classification group separately.

f) *Further Topics to Be Canvassed*

This is the first of a series of formal documents that the advisory council plans to prepare on the subjects of the interpretation of health effects data and the role of economic analysis in the standard setting process. Among the issues to be canvassed in future advisory memoranda are the following:

i) Principles and procedures for the interpretation of animal data.
ii) Principles and procedures for the extrapolation of animal data to humans.
iii) Principles for determining the weight to be accorded to human, animal and other biological data for use in the standard-setting process.
iv) The kinds of economic information that should be collected and analysed in the process of developing regulations.
v) The manner in which health effects and economic information should be integrated in the regulation of harmful agents.

It is expected that these topics will be addressed in the advisory council's *Sixth Annual Report.*

Footnotes

1. See, in this regard, R. Roberts, Methodological Review and Summary of Epidemiological Studies of Asbestos Exposure— Mortality Studies with Environmental Data. April, 1982; D. Sackett *et al.*, eds. Compliance with Therapeutic Regimens. (Baltimore, Maryland: The Johns Hopkins University Press, 1976); H. Shannon, Categorization of Statements on Asbestos Related Diseases. Paper submitted to the Canadian Centre on Occupational Health and Safety, May 11, 1982; J. Schlesselman, Case Control Studies—Design Conduct, Analysis. (New York,

New York: Oxford University Press, 1982); and N. Breslow *et al.*, Statistical Methods in Cancer Research. (Lyon, France: International Agency for Research on Cancer, 1980).

2. For the reader who seeks further information on this subject, the publication by J. Schlesselman, *ibid.*, considers the criteria that should be employed to judge the quality of case control studies.
3. For an example of this approach, see R. Roberts, *ibid.*, p. 2.
4. See for example, H. Shannon, *ibid.*, p. 170.
5. Sir Austin Bradford Hill. The Environment and Disease: Association or Causation. In: Proceedings of the Royal Society of Medicine, Section on Occupational Medicine, p. 295.
6. D. Sackett. A Review of Diagnostic Tests for Causation. Paper prepared for the Ontario Royal Commission on Asbestos, Dec.12, 1980, p. 9.

Acknowledgements

The membership of the task force originally included three members of the advisory council and five outside experts. The council members were: Professor R. D. Fraser (chairman), Mr. L. Heard and Dr. E. Mastromatteo (until his term as an advisory council member expired on October 31, 1982). The outside experts were: Dr. Gordon Atherley (with Dr. J. Purdham as official alternate) (Canadian Centre for Occupational Health and Safety), Dr. E. Farber (University of Toronto), Ms. L. Jolley (consultant), Professor R. Roberts (McMaster University) and Professor C. Tuohy (University of Toronto). Mr. A. Gladstone served as an ex officio member of the task force, representing the Ontario Ministry of Labour. In its deliberation, the task force also met with Mr. N. Lockington (Dominion Foundry and Steel Company) and Dr. M. Nazar (Chief, Occupational Health Laboratory, Ontario Ministry of Labour) who provided invaluable advice on criteria for judging the quality of environmental monitoring techniques and laboratory sampling procedures.

The advisory council would also like to thank Professor R. Roberts, whose framework for the evaluation of epidemiological studies served as the model for the task force's subsequent work.

Ontario

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March 16, 1983

Dr. J.F. Mustard, Chairman
Advisory Council on Occupational Health
and Occupational Safety
400 University Avenue
Toronto, Ontario, M7A 1T7

Dear Dr. Mustard:

Thank you for your letter of February 14, 1983, submitting to me Advisory Memorandum 82-V on "Principles and Procedures for the Interpretation of Epidemiological Studies".

I look forward to receiving the detailed appendix to the Memorandum which, I understand, is expected by March 21, 1983.

You may expect to receive my formal response to the Memorandum, as soon as it has been reviewed in the light of the appendix.

Yours sincerely,

R.H. Ramsay
Minister

Ontario

Advisory Council on
Occupational Health &
Occupational Safety

Office
of the
Chairman

400 University Avenue
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416/965-2448

April 8, 1983

The Honourable Russell H. Ramsay,
Minister of Labour,
400 University Avenue,
14th Floor,
Toronto, Ontario.
M7A 1T7

Dear Mr. Minister:

I am pleased to submit, for your consideration, the appendix which accompanies Advisory Memorandum 82-V on Principles and Procedures for the Interpretation of Epidemiological Studies. This document was developed and approved by council's Task Force on the Interpretation of Health Effects Data and the Role of Economic Analysis in the Standard Setting Process.

I hope that you will find the contents of this document to be useful.

Yours truly,

J. F. Mustard, M.D.,
Chairman.

Enc.

c.c. to: T. E. Armstrong, Q.C.
Dr. A. E. Robinson

Appendix to
Advisory Memorandum 82-V
April 8, 1983

Task Force on the Interpretation of Health Effects Data and the Role of Economic Analysis in the Standard-Setting Process

1. CHARACTERISTICS OF THE DIFFERENT CLASSES OF OCCUPATIONAL MORTALITY STUDIES

The first portion of this appendix will discuss the attributes of the six classes of occupational mortality study designs listed in Figure 1 of the advisory memorandum, assess their strengths and weaknesses and provide criteria from which to evaluate the quality of individual research papers that fall within a particular design category.

a) The Randomized Control Trial

In this type of study, which is illustrated in Figure 1 of the appendix, individuals are randomly allocated to either i) receive or ii) not receive exposure to a particular environmental agent. Both the exposed and non-exposed groups are then followed forward in time to monitor the incidence of a particular outcome (e.g. death resulting from lung cancer). In general, the data obtained from a randomized control trial (RCT) provide the best evidence from which to judge whether a workplace agent is a causal factor in the development of a disease. Information derived from such a study is also accepted as having the least degree of bias. In the occupational setting, however, it is usually not possible (or ethical) to randomly allocate groups of workers to receive or not to receive exposures. Randomized control trials, however, could gainfully be employed to gauge the effects that certain protective measures have on the occurrence of occupational disease (e.g. whether a particular pattern of lighting will reduce the incidence of visual complaints among VDU workers). Although the RCT appears infrequently in the occupational health literature, this type of study design serves as the benchmark against which other classes of studies are judged.

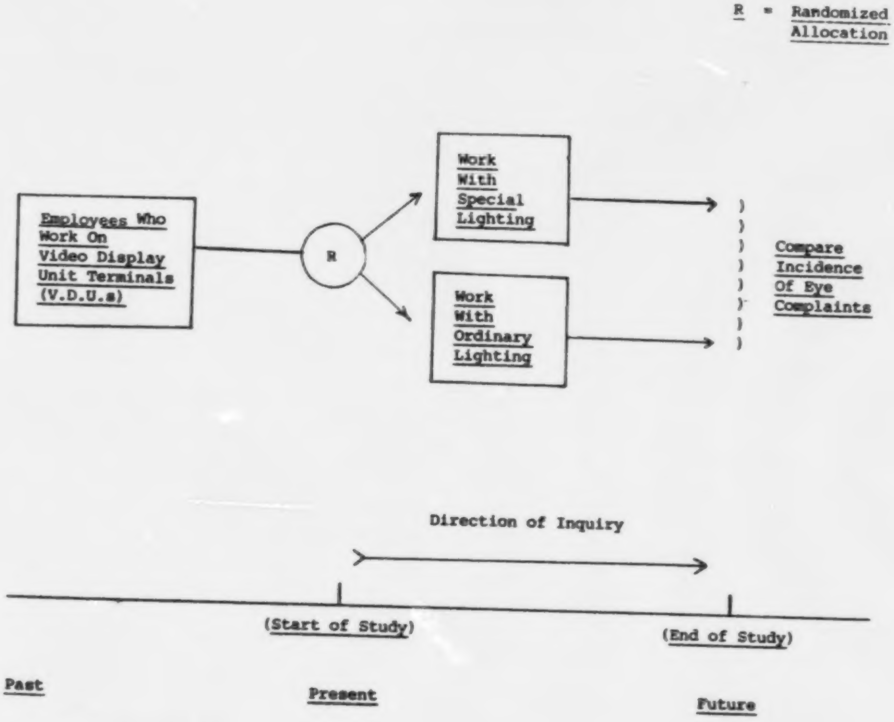
b) Prospective Cohort Studies

In prospective cohort studies, individuals who have been exposed to a workplace agent are followed forward in time. The mortality experience of these individuals is then compared to that of an external control group, which may either be a national or local population. In order to enhance the basis for comparison, some prospective cohort studies will also make use of an internal control group (i.e. a group of employees who work in the same plant as the cohort, but who are not exposed to the agent under investigation). The design of the prospective cohort study, which is illustrated in Figure 2, is broadly similar to that of the randomized control trial, except that the aspect of randomized selection is missing. In prospective cohort studies, workers 'self select' into the exposed and non-exposed groups. In this respect, one can never know for certain whether observed differences in mortality rates arise predominantly because of workplace exposures, or are the result of inherent differences in the two groups of workers.

Prospective cohort studies possess a number of methodological strengths. These may be summarized as follows:

i) The population at risk is defined.
ii) The extent of exposure to which cohort members are subject can be documented accurately.
iii) Study subjects themselves (or their close relatives) can be contacted when necessary to obtain supplementary information.
iv) The study design permits one to calculate mortality rates.

Figure 1: SCHEMATIC ILLUSTRATION OF A RANDOMIZED CONTROL TRIAL

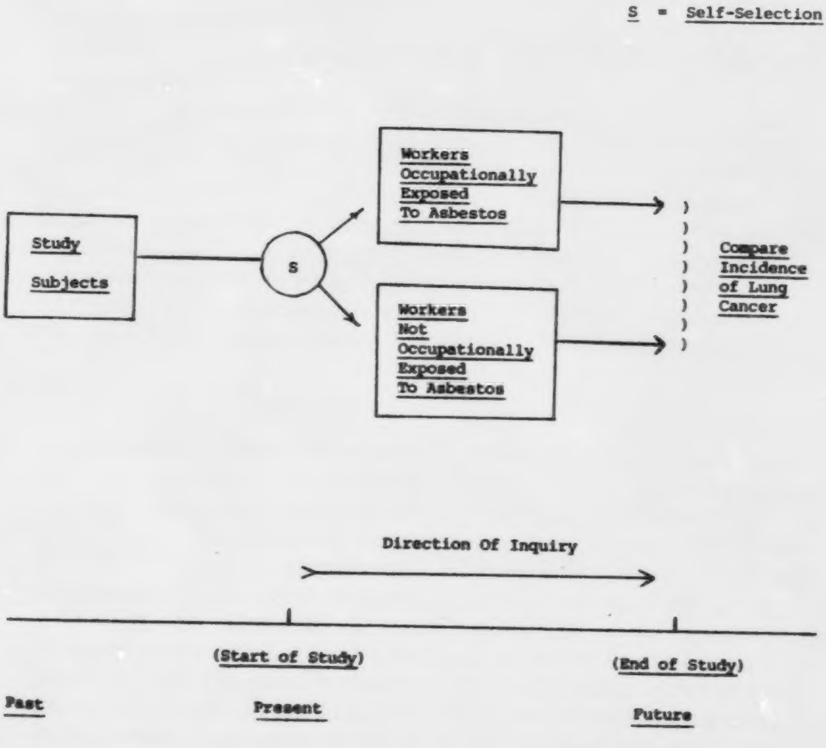

R = Randomized Allocation
Employees Who Work On Video Display Unit Terminals (V.D.U.s)
R
Work With Special Lighting
Work With Ordinary Lighting
Compare Incidence Of Eye Complaints
Direction of Inquiry
(Start of Study)
(End of Study)
Past
Present
Future

This class of study also exhibits a number of shortcomings, however. Some of these are:

i) The follow-up period for such studies may have to extend over many years in order to take into account the slow clinical manifestation of disease.
ii) The choice of the national population as a control group may be inappropriate, especially in those situations where the cohort comes from a geographicial region characterized by distinct mortality patterns.
iii) Prospective cohort studies are usually more costly and require more subjects than most other classes of studies.

Because prospective mortality studies proceed forward in time, and since many years may elapse between exposure to an agent and the onset of disease or death, this type of study design is found only rarely in the context of occupational epidemiology.

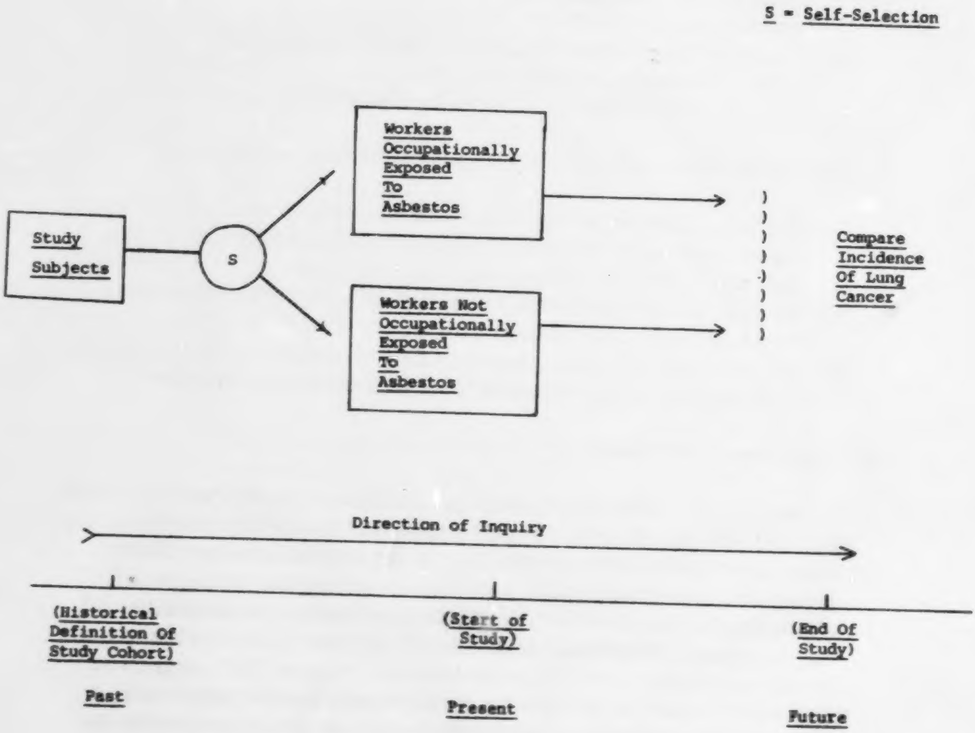
Figure 2: SCHEMATIC ILLUSTRATION OF A PROSPECTIVE COHORT STUDY


S = Self-Selection
Workers Occupationally Exposed To Asbestos
Study Subjects
S
Workers Not Occupationally Exposed To Asbestos
Compare Incidence of Lung Cancer
Direction Of Inquiry
(Start of Study)
(End of Study)
Past
Present
Future

c) Historical Prospective Cohort Studies

Historical prospective cohort studies are similar to the 'true' prospective cohort studies discussed above. However, instead of following workers forward in time for many years to gauge the effects that occupational exposures may have on mortality, a cohort of workers is identified at some point in the past and then followed through to the present. The mortality experience of the cohort is then compared with that of an external control group, which is most often the general population. In this type of study, cohorts who have been exposed to environmental agents are normally identified from company employment records. Exposure information is, in turn, derived from job histories and from environmental measurements taken at the plant site. The design of the historical prospective cohort study is illustrated in Figure 3.

Figure 3: SCHEMATIC ILLUSTRATION OF A HISTORICAL PROSPECTIVE COHORT STUDY


S = Self-Selection
Study Subjects
S
Workers Occupationally Exposed To Asbestos
Workers Not Occupationally Exposed To Asbestos
Compare Incidence Of Lung Cancer
Direction of Inquiry
(Historical Definition Of Study Cohort)
(Start of Study)
(End Of Study)
Past
Present
Future

The most frequently employed method of evaluating mortality in a cohort of exposed workers is to calculate the Standardized Mortality Ratio (SMR) for the group. The SMR is the ratio of observed deaths in a cohort divided by the number of deaths that would normally be expected in a group with a similar age distribution. The denominator of the statistic (i.e. the expected number of deaths) is computed in the following manner:

i) A calculation is made of the 'man-years at risk' in the cohort (i.e. the number of individuals in the cohort multiplied by the number of years that each individual has been followed forward in time).
ii) The man years at risk figure is then multiplied by the mortality rate for the disease(s) being considered.

Mortality rates are normally obtained from national population statistics. An SMR of 120 for a particular cause of death (e.g. lung cancer) indicates that, although one would have expected to find a total of 100 such deaths within a population group, one has, instead, observed 120.

The major advantages of historical prospective cohort studies may be summarized as follows:

i) These sorts of studies can produce more timely results ordinarily at less cost than prospective cohort designs.
ii) The historical prospective cohort approach is more sensitive to modest elevations in excess mortality than some other sorts of research designs (e.g. the proportional mortality study).

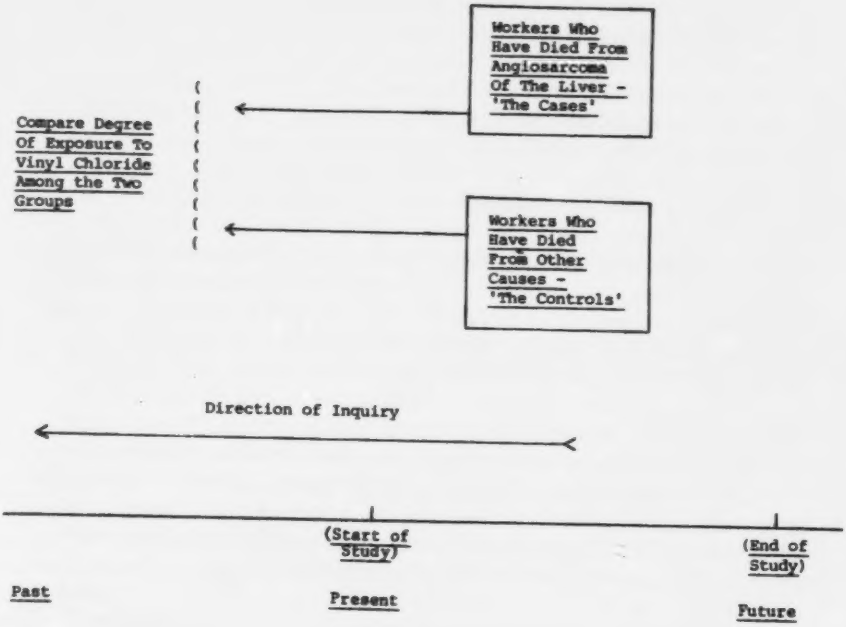
Among the shortcomings of this type of study are the following:

i) The identification of the cohort, the quantification of exposure and the ascertainment of mortality are all based on historical records that may be incomplete or otherwise inadequate.
ii) As in the case of prospective cohort studies, the national population may not be a suitable control group.
iii) The only demographic variable ordinarily considered in the calculation of SMRs is age,[1] whereas other factors may also be relevant.

d) Case-Control Studies

In this type of study, which is depicted in Figure 4, individuals who have contracted a particular disease (the cases) are matched to another group (the controls) that is free of the disease under consideration. The two groups are then traced backwards in time to compare the degree of exposure that members of each group have had to a suspected disease causing agent. If the study demonstrates that the cases were more apt to come into contact with the agent than were the controls, a suggestive link may be established between the agent and the disease. In case control studies, it is essential that the cases and controls resemble one another to the fullest extent, except for the presence of the disease.

Figure 4: SCHEMATIC ILLUSTRATION OF A CASE CONTROL STUDY


Workers Who Have Died From Angiosarcoma Of The Liver - 'The Cases'
Compare Degree Of Exposure To Vinyl Chloride Among the Two Groups
Workers Who Have Died From Other Causes - 'The Controls'
Direction of Inquiry
(Start of Study)
(End of Study)
Past
Present
Future

The main advantages inherent in the case control approach may be summarized as follows:

i) Studies of this sort can be conducted relatively quickly and at low cost.
ii) Case control studies may not require as many subjects as are needed in cohort studies.
iii) The case control approach may be more attractive when a) researchers must review a wide variety of factors that may be responsible for a disease state, or b) the disease under consideration is rare.

The case control approach, however, suffers from a number of serious methodological deficiencies. These are set out below:

i) The design of case control studies does not permit the researcher to define populations at risk of contracting a particular disease (as a result it is not possible to calculate SMRs for study groups).

ii) Since case control studies employ the interview method to obtain information on the exposure histories of cases and controls, the data collected may be inadequate or subject to errors or biases of recall (i.e. persons who have contracted an occupationally induced disease may more readily recall exposure to possible factors of interest than will members of the control group).[2]

iii) Problems may arise in the selection of an appropriate control group.

It should be noted that case control studies are seen only rarely in the formal literature on occupational health.

e) Proportional Mortality Studies

In this type of study, one compares the proportion of deaths obtained for a given cause in an exposed group with the proportion that would be expected for the same cause of death in the general population. To compute the number of deaths expected for a specific cause in a study group, one would first calculate the proportion of deaths from this cause that occur in the general population. Next, one would multiply the total number of deaths observed in the occupational group by this percentage. The figure so obtained is usually refined by dividing members of the study group according to age at death and year of death. The latter piece of information is judged necessary since patterns of mortality vary from period to period. If the number of deaths observed for a particular cause of death exceeds the number of deaths expected, then there is some evidence of an increased risk. The magnitude of the risk can be expressed as the proportional mortality ratio (i.e. observed deaths divided by expected deaths).

Since proportional mortality studies are based on mortality information alone, they may be conducted in an expeditious fashion at relatively low cost. Studies of this type are particularly useful for general survey purposes and will often be followed by more sophisticated epidemiological research. Proportional mortality studies, however, possess a number of serious methodological deficiencies. These may be summarized as follows:

i) The company benefits files, from which information on observed deaths is ordinarily obtained, may not provide a representative sample of all employees who have ever worked in a plant and, more importantly, those who may have died before the study was undertaken.

ii) Proportional mortality studies usually do not make provision for an internal (i.e. an in company) control group.

iii) Because of design limitations, such studies are unable to define populations at risk and, like case control studies, it is not possible to calculate SMRs.

As a result of (i) and (ii) above, proportional mortality studies lack the sensitivity to detect all but sizeable levels of excess risk.

f) Case Series Studies and Case Reports

A case series study is a work that describes the characteristics of a group of patients who are suffering from a particular disease. Ordinarily, these individuals will have attended one medical practitioner or a clinic. In addition, their health status will usually be described according to possible causitive exposures or risk factors. In a typical case series study, a researcher would report that (X) per cent of all individuals found to be suffering from a particular disease had been exposed to an identified environmental agent. The association might become evident in a number of ways. For example, the disease in question might be rare or might exhibit a characteristic that suggests some relationship to the occupational environment. A case report is similar to a case series study, except that only one occurrence of a disease is analysed. Neither the case series nor the case report approach provides control groups for purposes of comparison.

2. CRITERIA FOR EVALUATING THE QUALITY OF TWO CLASSES OF OCCUPATIONAL MORTALITY STUDIES

Tables 1 and 2, which appear in the advisory memorandum, list criteria for evaluating the two most common classes of study designs encountered in the occupational mortality field, namely historical prospective cohort and proportional mortality studies. The second portion of the appendix will elaborate in detail on the contents of these tables and suggest how a study could fulfil each of the criteria.

a) The Evaluation of Historical Prospective Cohort Studies

As is outlined in Table 1, the framework for analysing historical prospective cohort studies is made up of four sets of evaluative criteria. These deal respectively with the definition of the study cohort, the quantification of exposure, the ascertainment of mortality and the analysis of results.[3] Each set of criteria is, in turn, sub-divided in order to permit a more detailed form of methodological analysis.

i) *The Definition of the Study Cohort*

The key consideration in the definition of a study cohort is that the subjects selected will provide reliable data on the exposures and subsequent health outcomes of workers who were exposed to an environmental agent at a particular job site. The definition of a study cohort has four principal aspects: the method of cohort selection, criteria for inclusion or exclusion of cohort members, the extent to which the subjects selected for study include all eligible workers and the adequacy of the size of the cohort. Each of these features will now be considered.

The method of cohort selection should endeavour to identify subjects, through a uniform process, at an early stage in their exposure histories. The favoured approach is to bring workers into a study from the point in time at which they commence employment at a particular plant. A group of subjects defined in this manner is referred to as an inception cohort. A major advantage in selecting an inception cohort is that all workers who have come into contact with an environmental agent are identified before adverse health effects are likely to arise. A less satisfactory method of cohort selection is to consider only those workers who were employed in a plant at a given point in time. This is referred to as a cross-sectional approach and tends to be more prone to bias. The major concern in this regard is that workers with early signs of an occupational disease may have left the plant before the study was conducted. As a result, the magnitude of risk associated with an environmental agent could be underestimated. In this respect, it is important for a historical prospective cohort study to provide details on the method employed to select subjects for inclusion in a study group.

Once a suitable cohort has been identified, a decision must be made with respect to whether all members of the group should be considered for study purposes. Most historical prospective cohort studies apply a minimum service requirement to members of the cohort. That is to say, unless a worker has been employed at a particular plant site for a given period of time, the worker will be excluded from the study. There are essentially two reasons why researchers favour the use of a minimum service requirement:

a) Workers who are employed in plants for only short periods of time are more likely to be transient and, therefore, difficult to follow up,

b) Workers with very brief exposures to environmental agents are unlikely to suffer adverse health effects as a result of such exposures (as a result, the presence of these individuals in the cohort might obscure the cause and effect relationship being sought).

In those situations where the agent under investigation has already been linked to excess mortality, short minimum service requirements (as little as one month) are normally applied to permit researchers to determine whether adverse health effects are demonstrated in workers with low cumulative exposures. Where, on the other hand, little is known about the association between an agent and a particular disease outcome, a longer minimum service requirement (up to several years) may be employed in order to determine whether an increased mortality rate is evident among the most heavily exposed workers. If only long-term employees are considered, however, there is the risk that workers who have left the plant because of occupational exposure will be ignored. It should be noted that some studies also exclude younger subjects from the cohort to be investigated. This decision, which may not always be appropriate, is based on the assumption that, given a finite period of follow-up, younger employees would not be expected to exhibit the same degree of excess mortality as would be recorded in older members of the cohort. In evaluating any historical prospective cohort study, it is therefore necessary to examine both the criteria and rationale for including or excluding workers from a study cohort.

A related methodological consideration relates to the completeness of the study population. In analysing a historical prospective cohort study, one must ask whether all eligible subjects were considered, or only a sample thereof. The ideal study design would bring all workers into the investigation, subject to the minimum service requirements noted above. Where a sample of workers is chosen, however, the selection should be made through a random process in order to avoid the likelihood of obtaining a biased sample. The reviewer should carefully examine the steps taken in a study to ensure that the employment records of all cohort members have been considered.

The final factor to be taken into account in the evaluation of a study cohort is the cohort's size. In general, the sensitivity (power) of a study to detect excess risk is related directly to the size of the cohort. While it is difficult to make a categorical statement about the number of subjects that should ideally be included in a historical prospective cohort study, the cohort should be large enough to have a good chance (greater than 80 per cent) of detecting a true increase in the level of mortality. A more detailed discussion of statistical power will be presented in a later section of this appendix.

ii) Quantification of Exposure

Accurate estimates of the exposures to which workers have been subjected will improve the overall quality of historical prospective cohort studies. In order to judge whether exposure data presented in a study are satisfactory, four criteria should be considered: the amount of detail contained in work history files, the extent of industrial hygiene data, the quality of industrial hygiene data and whether the likely impact of confounding factors is discussed. Each of these criteria will now be examined in greater detail.

Work history files, to be judged satisfactory for epidemiological purposes, should provide fairly detailed information on the jobs held by individual employees at a given work site. The geographic location of a job assignment within a particular plant as well as the duration of the assignment are of particular importance. High quality employment records will also contain data on significant periods away from the job (e.g. as a result of sickness or lay-offs). The limiting feature of most work history files is, however, that particular job titles do not provide adequate information on the type of work performed by individual employees. It is often difficult, therefore, to state with certainty that a worker was actually employed at a specific job site for a defined period of time and was, thus, exposed to the level of environmental contaminants calculated for that location. In assessing the quality of work history files, the reviewer should search the methods section of a study for a discussion of the type of information contained in these records.

The extent of the industrial hygiene data available to estimate exposures is also an important factor to consider. In general, the greater the number of measurements taken, the more confidence one can have that industrial hygiene data of a given type have not over or underestimated workplace exposures. This statement must, of course, be qualified by the observation that different categories of industrial hygiene data tend to vary markedly in terms of quality, depending on the sampling methods employed. In this respect, fewer samples obtained through a superior monitoring technique may provide more reliable data on workplace exposures than more numerous samples conducted through less sound procedures. Although it is difficult to state, as a matter of convention, the number of samples that should be obtained in order to accurately assess exposures at a job site, the standard of excellence adopted by industrial hygienists would require that measurements be taken, at regular intervals, over a period of 10 working days.[4] As a general rule, workplaces characterized by fluctuations in airborne exposure levels should be sampled more frequently than stable environments. Repeated monitoring of this nature is required to calculate average exposures and peaks. In addition, where a plant is located in a climatic region characterized by sizeable temperature variations depending on the season, it would be desirable to conduct sampling at periodic intervals over the course of the year. This is the case because sampling carried out exclusively during the winter months may overestimate average annual exposures since doors and windows tend to be closed, thereby reducing ventilation, and because heated air is often recirculated. Similarly, sampling conducted only during the spring or summer months may tend to underestimate exposures since air circulation will generally be above average, thereby diluting the concentrations of agents typically found in the environment. Furthermore, where exposures are apt to vary in different sections of a plant, samples should be obtained from each of these locations.

It should be noted that while the calculation of average exposures is typically employed as a means of gauging a worker's intake of an environmental agent, other parameters of exposure may have equal or greater relevance (e.g. time spent above a peak exposure limit). In this respect, it would be desirable for industrial hygiene data to contain complete information on the nature and extent of exposures encountered in the workplace.

The confidence that one can place in the exposure estimates set out in occupational mortality studies depends, to a large extent, on the quality of the industrial hygiene data upon which these estimates are based. Three factors to consider in assessing the quality of industrial hygiene data are: a) the type of sampling strategy employed (e.g. area monitoring, personal monitoring, etc.), b) the sampling techniques utilized, and c) the methods by which samples are analysed. With respect to sampling strategies, it is important to distinguish between three parameters of measurement: area concentrations, worker exposure levels and dose. The term 'airborne concentration' refers to the amount of a substance found to exist in a particular sampling location per unit of air. The term 'worker exposure level', on the other hand, describes the amount of a substance that employees are actually inhaling. These levels are calculated by obtaining samples from the breathing zones of workers. The final concept of interest, namely, 'dose', refers to the amount of a substance that an individual is actually absorbing. In some cases the exposure level recorded for a worker may correlate well with dose. In other situations, however, the correlation may be imperfect since a) some contaminants may enter the body by ingestion or through the skin, b) different workers may have varying susceptibilities to particular agents, and c) the degree of exertion on the job (which influences both the rate and depth of breathing) may cause workers to inhale and, subsequently, absorb larger or smaller amounts of a substance than would ordinarily be expected. It should be emphasized that, in the great majority of cases, only a fraction of the contaminant to which a worker is exposed will actually be absorbed.

There has been a tendency in some occupational mortality studies to relate airborne concentrations to worker exposure levels. It would appear, however, that a one-to-one relationship of this sort will rarely exist. That is the case because a) area and personal monitoring are usually conducted in different plant locations, thereby producing non-identical readings, and b) personal exposures tend to be more variable on a day-to-day basis.[5] As a general rule, exposure data based on personal monitoring is to be preferred over similar data obtained through area monitoring techniques.

Because of the great variability in the scope of procedures employed to measure levels of contaminants in the air, it is difficult to set out comprehensive guidelines for judging the quality of individual monitoring techniques. Rather, in the evaluation of occupational mortality studies that focus on particular disease causing agents, the reviewer must analyse the sampling procedures employed according to (a) the physical characteristics of the agent under consideration, (b) the nature of the health effect being examined, and (c) the range of monitoring techniques available to record exposures to the agent. Particular importance should be paid to the sampling device used, the counting method employed and the accuracy of the monitoring technique. In addition, when the method used to monitor exposures in a workplace has changed, the reviewer should look for side by side comparisons of the old and new techniques in order to establish a conversion factor. Another useful piece of information to take into account in studies relying upon personal monitoring techniques is the percentage of cohort members who have actually been sampled. Assuming that the sampling location is appropriate, a procedure will generally be deemed to provide accurate exposure data where the sampling error attributable to monitoring equipment is no greater than plus or minus 10 per cent.[6]

In judging the quality of the analytical (laboratory) techniques used to evaluate industrial hygiene data, a number of factors should be considered. These factors are:

a) The specificity of the analytical method (i.e. the extent to which the result obtained could only have been caused by the agent under investigation and not by others).
b) The steps taken to control external influences, where these influences could affect test results.
c) The accuracy of the analytical method (i.e. the extent to which the procedure reflects actual exposures received).
d) The precision of the analytical method (i.e. the extent to which the

procedure provides the same result on a consistent basis, irrespective of whether the result is accurate).

e) Whether the test results are reproducible (i.e. will a similar result likely be obtained when an analytical procedure is repeated in the same laboratory?).

f) Whether test results are repeatable (i.e. will a similar result likely be obtained when an analytical procedure is repeated in a second laboratory taking into account differences in techniques, operator experience and environmental conditions?).

g) Whether test results have been analysed in an accredited laboratory.

h) Whether the analytical methods employed are fully described in the study.[7]

It is apparent to task force members that the analysis of exposure data is a complex task that demands specific expertise in the fields of industrial hygiene and laboratory analysis. In this respect, the task force believes that among the government staff assigned to evaluate the strengths and weaknesses of competing health effects studies there should be included, where appropriate, professionals with formal training in laboratory analysis and the assessment of environmental exposures.

In order to gauge the true impact that exposure to a workplace agent has on the health of an employee population, the effects of confounding factors must be considered. A confounding factor is a variable that ordinarily a) has a causal relationship with the outcome of interest, and b) is distributed unequally among members of the exposed and non-exposed study groups. Confounding factors may be either occupational or non- occupational in nature. The degree to which the effects of confounding factors should be examined in an epidemiological study depends largely on the disease outcome in which one is interested. For example, if one were investigating the relationship between exposure to the solvent methylethylketone and the incidence of nerve damage, it would be useful to determine whether study subjects had also been exposed to the solvent n-hexane. This is the case because the effect on the nervous system produced by simultaneous exposure to both substances is considerably greater than the sum of the individual effects of each agent.[8] Similarly, in the case where asbestos related lung cancer is being studied, it would be helpful to have data on the smoking habits of all study participants (i.e. members of both the cohort and the control group). One could then adjust for differences between the two groups and compare lung cancer rates on the basis of exposure to the confounding factor (e.g. smokers in the cohort could be compared to smokers in the control group, etc.). A less satisfactory method of controlling for the effects of smoking would involve studying only those individuals who abstained from this activity. An approach of this sort, however, would limit the degree to which the results obtained from the study could be generalized. Where historical data on smoking patterns are unavailable, a further option (judged least desirable from a methodological standpoint) would be to survey the smoking habits of workers currently employed in the industry being studied. The prevalence of smoking among these workers would then be compared to the rate in the general population. If the smoking habits detected are fairly similar, then researchers can put forward the argument that smoking patterns alone are unlikely to explain observed differences in lung cancer mortality rates.

The characterization of smoking as a confounding factor in the preceding example is not meant to cloud or to downplay the demonstrated relationship between exposure to asbestos and the impact on health status. Rather, the example is intended to suggest that until the relative contribution of smoking to asbestos-related lung cancer is accurately documented, persons who seek to minimize the risks of asbestos will be able to over-emphasize the possible influence of smoking.

It is important that the effects of confounding factors on mortality be considered not only for the cohort under study but also for the control group. Where this practice is not followed, an additional bias may be built into the results of a study. It should be noted that most epidemiological studies do not analyse the impact of confounding factors in a satisfactory fashion.

iii) Ascertainment of Mortality

In order to determine whether exposure to an environmental agent has an effect on the incidence of mortality within a cohort, one essentially needs to know how many cohort members have died, when they died and what they died of. Collectively, these considerations may be labelled as the ascertainment of mortality. To judge whether a study has, in fact, adequately taken into account, and classified, deaths in a workplace population, four separate factors need to be considered. These are a) the quality of the follow-up technique (i.e. the method employed to determine whether subjects are alive or dead at the end of a study), b) the completeness of the follow-up procedure, c) the availability of death certificates or other records that list causes of death, and d) the length of the follow-up period.

The quality of the follow-up technique employed in a historical prospective cohort study will depend heavily on the availability of adequate mortality data. In those situations where a worker is employed by a company until death, retirement or the vesting of pension rights, company death, benefit or pension files can be scrutinized to determine whether the worker is still alive. Ordinarily, however, a sizeable proportion of study subjects will have left a company before any of these events have occurred. It will therefore become necessary to rely on official (i.e. governmental) sources of mortality data, the quality of which may vary from country to country. The data systems maintained in the Scandinavian countries and in Britain are generally thought to be the most reliable for ascertaining mortality status. The official data sources that are available in Canada and the United States are considered to be somewhat less adequate. In order to supplement the information obtained from official sources, some studies employ tracing techniques to locate individual workers or, if they are dead, relatives who can provide information on mortality status. Individual tracing is generally regarded to be the most effective approach for determining the incidence of death in working populations.

A historical prospective cohort study will be considered excellent in the context of mortality ascertainment where it is able to follow up 95 per cent or more of the members in a cohort. High rates of follow-up are considered crucial since research has shown that the incidence of mortality among workers who are difficult to trace tends to be higher than the mortality incidence of workers who are easier to follow up.[9] If a sizeable number of individuals from the former category are not included in a study, there is the risk that the results obtained may underestimate the number of deaths that have actually occurred in the cohort. For this reason, follow-up rates of less than 90 per cent are judged to be unacceptable.[10]

Once the researcher has determined that a subject is no longer alive, the next step is to ascertain the cause of death. Information of this sort is ordinarily contained in death certificates, whose availability and overall quality vary from country to country. In Britain, Scandinavia and Canada death certificates are readily accessible. In the United States, however, difficulties may arise on occasion in locating a sufficient number of certificates for study purposes. When death certificates for some cohort members cannot be found, any cause specific analysis of mortality patterns within the cohort will remain incomplete. Furthermore, if the likelihood of not locating a certificate varies with the cause of death, any analysis that is conducted may produce misleading results.

The information contained in a death certificate may, from time to time, incorrectly classify the cause or causes of a worker's death. In those situations where researchers are investigating a specific type of disease (e.g. mesothelioma) whose broad symptoms resemble those of another disease (e.g. lung cancer) there may be the temptation to obtain additional information (gleaned from pathological specimens) to verify the correctness of the original diagnoses. The problem in pursuing this course, however, is that while the deaths of cohort members may be classified more accurately, a similar corrective procedure cannot usually be applied to the control group (i.e. the general public). In this respect, the selective reclassification of deaths might introduce an additional source of bias into the process by which the mortality patterns of cohort and control group members are compared.

The length of the follow-up period is the fourth factor to consider under the category of mortality ascertainment. In selecting an appropriate follow-up period, the objective is to ensure that a sufficient number of subjects are observed well beyond the point in time when occupational diseases might be expected to arise. When choosing a follow-up period, the researcher must weigh two important considerations: the nature of the disease under investigation and the availability of employment and exposure records. As a general rule, the quality of such records deteriorates as one proceeds further back in time. Where the disease under consideration is cancer or where the researcher does not know what diseases might be induced as a result of exposure to a particular environmental agent, a follow-up period of at least 30 years should be selected. A time frame of this sort is necessary in order to take account of the often lengthy time periods that precede the clinical manifestation of some diseases. The failure to provide for an adequate follow-up period may cause a study to underestimate the health risks posed by an environmental agent. Furthermore, the results obtained from such a study will not support the proposition that exposure to the agent in question will not produce any adverse health effects.

iv) Analysis of Results

In determining whether the results of a study have been analysed in a satisfactory manner, six factors need to be considered. These are: a) the appropriateness of the external control group employed in the study, b) the availability of an internal control group, c) whether the study takes into account the latency periods associated with disease development, d) the use of appropriate statistics, e) the demonstration of an exposure gradient, and f) a discussion of possible sources of bias.

a) External Control Group

As indicated earlier in this working paper, most historical prospective cohort studies employ an external, rather than an internal, control group for the purpose of calculating the expected number of deaths for a study population. The external control group is typically made up of members of a national population group. Less frequently, however, a local population group may be employed for comparative purposes. In determining whether mortality statistics should be drawn from national or local sources, one must take the following considerations into account:

i) In order to accurately estimate the expected number of deaths in a population by cause, a very large control group may be required.
ii) Where the geographic region in which a plant is located is characterized by distinct mortality patterns, a more accurate estimate of expected deaths will likely be obtained where the control group is drawn from the same area.
iii) Where a geographic region has essentially one major work operation, and where the subjects for an epidemiological study are to be drawn from a segment of this working population, it would be preferable if the control group were not drawn exclusively from this geographic location. That is the case because some members of the control group may have been exposed to the environmental agent under investigation.

In short, while the use of national data enhances one's ability to calculate expected mortality rates for a wide spectrum of diseases, the application of local data may reduce possible sources of bias when cohort and control groups are compared. The choice of one or the other approach will likely be dictated by the nature of the study being undertaken and the availability of mortality data. Ideally, expected deaths should be calculated on the basis of both local and national statistics.

Whenever external control groups are employed for comparative purposes, there is the risk that members of the control groups will differ from subjects in the cohort, not only in terms of occupational exposures, but with respect to other factors as well. It has been shown, for example, that workers who are hired for jobs tend to be more fit than members of the general population, whose ranks include the sick and disabled. As a result, the risk of mortality tends to be higher in the general population, when compared to a cohort of workers. For example, among workers employed in safe working environments the risk of mortality may be from 10 to 40 per cent lower than that encountered in the general population.[11] As a result, the SMRs calculated for employee cohorts will often be lower than 100 (the value fixed for the general population) before the effects of exposure are taken into account. The difference in mortality risk, caused by the fact that fit workers tend to be more employable, is referred to as the healthy worker effect. Within hazardous industries, the operation of the healthy worker effect will ordinarily be most pronounced when job applicants first commence employment. The SMRs will then presumably rise as the workers are exposed to harmful environmental agents. It should also be noted that the healthy worker effect will generally have a greater impact in cohort groups that include many young workers.[12] In evaluating the results of historical prospective cohort studies, it is therefore important to review the manner in which the authors have dealt with this potential source of bias.

b) Internal Control Group

In order to minimize the impact of the healthy worker effect, some studies make use of an internal control group rather than (or in addition to) an external control for comparative purposes. Depending on the characteristics of a company's work force, an internal control group may consist of in-plant workers who i) have not been exposed to the environmental agent under investigation, or ii) have suffered only limited exposures. The mortality experience of workers within the cohort and the control group are then compared. When an internal control group is used as the basis for comparison, all available health information can be employed, where necessary, to classify causes of death more accurately, provided that such reclassification is applied to both the cohort and the control group.

The healthy worker effect may also be addressed by conducting a supplemental case-control study in which one matches members of the internal control group who are still alive at the end of the study with members of the cohort group who have died of the disease being investigated. One then compares the exposure histories of both groups in an attempt to ascertain the risk posed by different degrees of cumulative exposure to an agent.

It should be recognized that while the use of an internal control group will ordinarily reduce the impact of the healthy worker effect, this source of bias may not be completely eliminated. That is the case because employees who are able to work in a hazardous exposure environment on a regular basis may be fitter than workers employed in the general plant population.[13] It should also be noted that, where workers in a plant move from job-site to job-site on a frequent basis, the use of an internal control may be inappropriate since it may be difficult to classify workers according to the cumulative level of exposures received. In addition, the fact that internal control groups will be smaller than control groups drawn from the general population will reduce the number of deaths available for classification purposes. Despite these shortcomings, however, and all other factors being equal, a historical prospective cohort study that utilizes an internal control group will be judged to have a higher level of inherent quality than a similar study that employs an external control group.

c) Latency

It has already been pointed out that some occupational diseases (notably cancer) will not exhibit clinical symptoms until many years have elapsed since a worker's initial exposure to a disease causing agent. This intervening time span, which is referred to as a latency period, must be taken into account in evaluating mortality rates for certain diseases. Should the effects of latency not be considered when a cohort's Standardized Mortality Ratio is being calculated (i.e. by including in the man-years at risk figure periods of time in respect of which subjects were not at risk of dying), there is the possibility that the impact of the disease causing agent being studied will be underestimated. The procedure normally employed to control for the effects of latency is to calculate man-years and deaths only after a fixed period of time has elapsed since first exposure. A period of 15 years is ordinarily selected when cancer is the disease of interest. Another method of dealing with the issue of latency is to sub-divide members of the cohort who have died of a particular disease on the basis of years since first exposure. This approach is particularly useful in those situations where controversy exists regarding the length of time required for disease development. A decision then needs to be made with respect to which cases should be excluded from the analysis. In reviewing a historical prospective cohort study, it is important that the reader ascertain whether the author has addressed the issue of latency, and whether this concept has been incorporated into the analysis of study results.

d) Statistical Analysis

The quality of a historical prospective cohort study will be enhanced where appropriate statistics are employed to analyse mortality data. The task force believes that five types of statistical procedures should be applied to evaluate the results of such studies. These procedures are:

i) The sub-division of man-years at risk according to such variables as age at death and calendar year of death.
ii) The use of statistical tests of significance.
iii) The calculation of confidence levels.
iv) Multiple testing.
v) The analysis of statistical power.

It will be useful to describe, in a summary fashion, each of the procedures listed.

i) Calculation of Man-Years at Risk

As indicated earlier in this paper, man-years at risk is the first factor that must be taken into account in the calculation of a Standardized Mortality Ratio. The man-years at risk figure, when computed for a cohort, represents the total number of years that members were at risk of dying from exposure to an environmental agent. In order to take into account the effects of aging and the changes in mortality patterns within the cohort over time, it is desirable that the man-years at risk total be sub-divided according to age and the calendar year of death. In practice, the data will ordinarily be presented in five-year packets (e.g. ages 20-24, 1970-1974, etc.). A cohort member will contribute man-years to successive age and calendar year 'boxes' as the worker is followed forward in time. The worker's contribution will cease when either a) the worker has died, b) the worker can no longer be located, or c) the follow-up period has come to an end. The objective of this exercise is to permit the calculation of age specific, calendar specific and cause specific observed mortality rates. To obtain the number of deaths expected for a disease in a cohort group, the man-years at risk figure is multiplied by a weighted mortality rate, which is drawn from general population statistics and which is corrected to take into account the age specific and calendar specific characteristics of cohort members. It should be noted that where additional information is available on cohort members (e.g. sex, race, lifestyle factors, age at first exposure, etc.) the analysis of SMRs may be enhanced.

ii) Tests of Statistical Significance

In analysing the associations revealed (or not revealed) in a historical prospective cohort study, it is important to know what confidence one can have in the results obtained. For example, where a study indicates that exposure to a particular workplace agent increases the likelihood of mortality from a particular disease, one would wish to know whether the association was real or arose due to chance alone. This is the issue of statistical significance. On the other hand, where a study fails to demonstrate a link between a workplace agent and a disease, it would be important to ascertain whether the study was sensitive enough to detect an excess risk that may, in fact, have existed. This is the issue of statistical power.

Tests of statistical significance endeavour to determine whether the number of deaths observed in a cohort (expressed as 'O') is unusually in excess of the number of deaths expected (expressed as 'E') after one takes into account the variability in mortality rates that will naturally exist in small study groups. The concept of statistical significance can be better understood through the use of an example. Let us suppose that 25 deaths have occurred within a cohort as a result of lung cancer when only 20 were expected. Utilizing a normal probability distribution* (which predicts the likelihood of a given number of deaths occurring in a cohort group of a given size through chance alone), and taking 20 as the mean expected number of deaths around which statistical variability will occur, it can be shown (see Figure 5) that there would be a 15.7 per cent chance of observing 25 or more deaths in the cohort through normal variability about the mean of 20 expected deaths. Although one cannot say that there is a 15.7 per cent chance that the observed excess is 'due to chance', one can interpret the data as being quite consistent with no elevation in risk. The 15.7 per cent figure (which is referred to as the p value of the test) is obtained by measuring the area of the normal probability distribution that falls to the right of the the figure for observed deaths.

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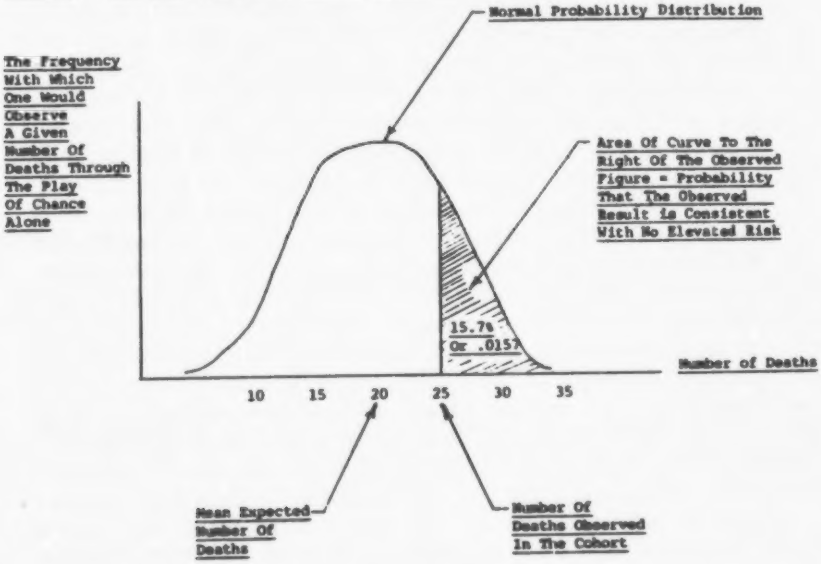
* The usual statistical assumption made is that the observed number of deaths follows a Poisson distribution, with the mean equal to the expected number of deaths. When E is greater than 5, however, many statisticians approximate the Poisson distribution by substituting a normal distribution with E equal to the mean and variance. The latter approach forms the basis for the discussion in this appendix.

As may be gleaned from the above example, the lower the p value (i.e. the more unusual the observed results would be if no risk was actually present), the stronger is the evidence that cohort members are exposed to an external risk factor. By convention, p values of 0.05 or lower are judged to be statistically significant. That is to say, researchers will generally regard study results to be persuasive where there is only a five per cent possibility that the results obtained (or more extreme results) could have occurred in the absence of a real risk. It should be emphasized, in this respect, that the failure to demonstrate that a test result is significant is not necessarily synonymous with the proposition that risk is absent. The choice of the 0.05 p value as the test for statistical significance is arbitrary since there is, in reality, little difference between p values of 0.055 and 0.045, even though the latter is considered statistically significant, while the former is not. In order to avoid interpreting test results in such a 'black and white' fashion, two approaches may be taken. The first is to publish the exact p values for a study and not merely the fact that results are significant. The second approach is to calculate confidence intervals for the observed data.

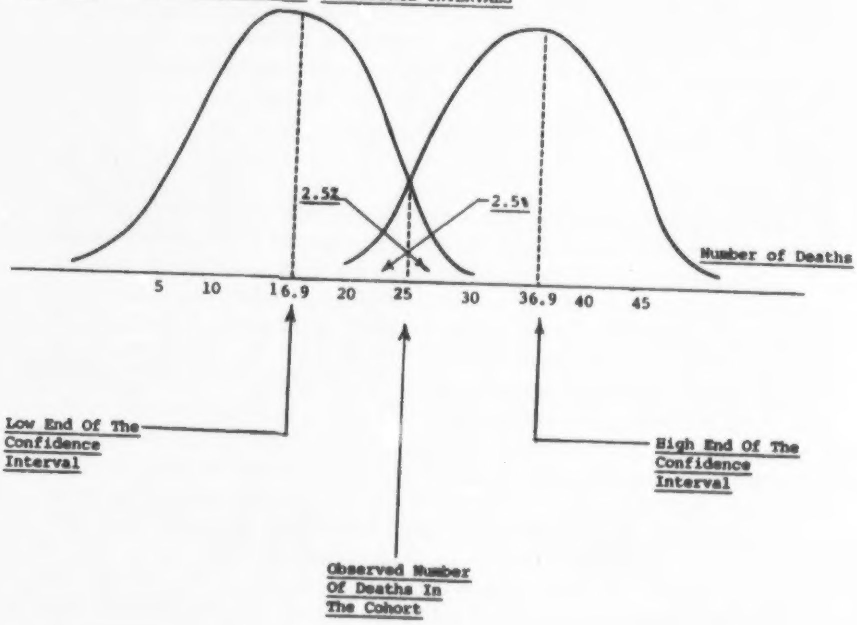
Figure 5: THE STATISTICAL COMPARISON OF OBSERVED VS. EXPECTED DEATHS



iii) Confidence Intervals

Confidence intervals permit researchers to ascertain the range within which the real SMR might be expected to fall given a) a cohort group of a particular size, b) a known number of observed and expected deaths, and c) a specified level of statistical confidence (normally a p value of 0.05). The method of calculating confidence intervals for a study cohort is illustrated in Figure 6. The first step is to compute the observed number of deaths for a cohort, which is 25 in our example. One then shifts the normal probability distribution to the left and right of the observed figure. The objective is to ascertain the high and low mean number of deaths which, if observed in study groups of the same size as our cohort, would make it unlikely, from a statistical standpoint, that 25 deaths would actually be recorded. For example, if a true risk factor produces an average of 36.9 deaths in such study groups, there would be only a 2.5 per cent chance that 25 or fewer deaths would occur in our cohort group. Similarly, where 16.9 represents the average number of deaths expected in theory, there would be only a 2.5 per cent chance that 25 or more deaths would occur in our cohort group (see Figure 6). Looking at the matter somewhat differently, when 25 deaths are, in fact, observed, it is statistically plausible that the expected number of deaths in the exposed group could range from 16.9 to 36.9. The final step in the exercise is to determine the confidence intervals for the SMR that was

Figure 6: THE CALCULATION OF CONFIDENCE INTERVALS


2.5%
2.5%
Number of Deaths
5
10
16.9
20
25
30
36.9
40
45
Low End Of The Confidence Interval
High End Of The Confidence Interval
Observed Number Of Deaths In The Cohort

calculated for our cohort (25 observed deaths/20 expected deaths = SMR of 125). The computation is performed in the following fashion:

$$100 \times \frac{\text{low end of observed death range}}{\text{expected deaths}} \qquad 100 \times \frac{\text{high end of observed death range}}{\text{expected deaths}}$$

$$100 \times \frac{16.9}{20} \qquad 100 \times \frac{36.9}{20}$$

$$85 \qquad 185$$

Thus, given an SMR of 125 for the cohort, the confidence interval for that statistic ranges from 85 to 185. This means that while the study has demonstrated an observed, over expected, ratio greater than 100, there is the possibility that no excess risk exists or, alternatively, that the risk is much greater. Wide confidence intervals of the type noted in this example are encountered frequently in small studies. The results of these studies will, typically, provide imprecise estimates of risk. It is important, in the task force's view, that confidence levels be calculated for all test results, whether or not they are found to be statistically significant.

iv) Multiple Testing

As indicated earlier in this section, when a p value of 0.05 is accepted as the measure of statistical significance, the researcher takes a one in 20 chance that an elevated risk will be detected in a cohort when such a risk is not present in reality. While a p value of 0.05 may be acceptable where only one test is conducted, the margin for error may become much greater where many tests are carried out. That is the case because the chances for error will tend to add up. For example, should 100 individual hypotheses be tested, one would expect to obtain five results that were statistically significant, even if no underlying risk existed. Two approaches may be employed to reduce the number of false positive results attributable to multiple testing. The first tactic is to separate what are known as *a priori* hypotheses from tests conducted for routine survey purposes. *A priori* hypotheses may be defined as relationships between environmental factors and the onset of particular types of disease, whose existence might be predicted on the basis of previous studies or biologic understanding. If the number of *a priori* hypotheses is small, the conventional p value of 0.05 may be applied to each. However, should a variety of *a priori* hypotheses suggest themselves or should a large number of associations be investigated for survey purposes, formal multiple testing procedures must be applied. In essence, such procedures are designed to ensure that the overall chance of obtaining one or more statistically significant test results in the absence of an underlying risk does not exceed one in 20. The simplest method employed to achieve this objective is to make the level for statistical significance more stringent. This can be done by dividing the conventional p value of 0.05 by k, where k represents the total number of tests conducted. Thus, if 10 such tests are carried out, each would have to attain a p value of 0.005 $\frac{(0.05)}{10}$ before the results would be regarded as statistically significant. Therefore, in reviewing the results of a study, one must ensure that multiple testing procedures have been employed where warranted.

v) Statistical Power

A related analytical issue concerns the evaluation of study results that indicate that members of a cohort group are not subject to increased risk as a result of exposure to an environmental agent. In reviewing such studies, it is important to consider whether excess risk was, indeed, absent or, alternatively, whether the study was simply not sensitive enough to detect such a risk. Lack of sensitivity can flow from a variety of factors,[14] the most important of which is the limited size of study groups. In order to assess the ability of a study to detect a real risk, epidemiologists measure the statistical power of the study. The method employed to calculate statistical power is illustrated in Figure 7. The first step is to draw a normal probability distribution with the expected number of deaths (in our case, 20) as the mean. Next, one calculates the number of deaths that would theoretically have to be observed to make the test result significant at the five per cent level (p = 0.05). This figure, which turns out to be 28.8, is referred to as the critical value. Now, suppose one wishes to know whether our study could reliably detect a real SMR of 150. To answer this question, one would superimpose a second normal distribution over the first, with a mean equal to 30 (the

Figure 7: THE CALCULATION OF STATISTICAL POWER

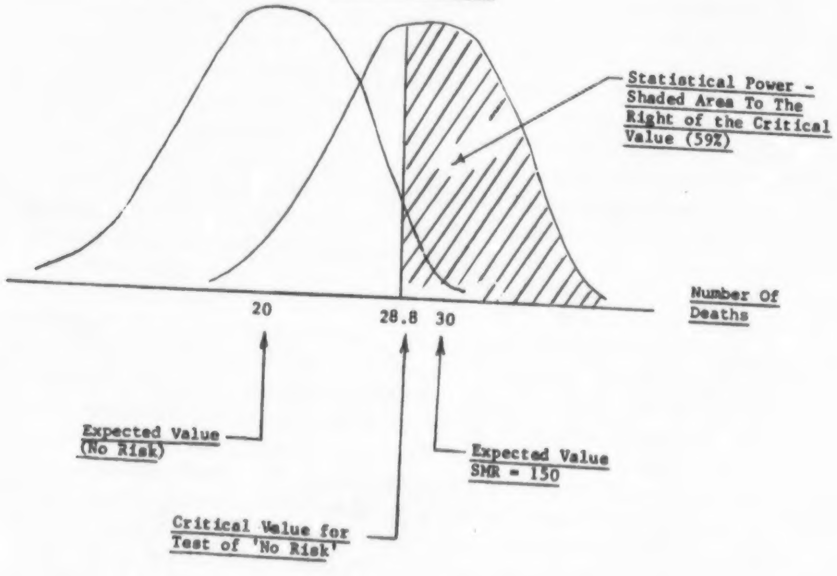
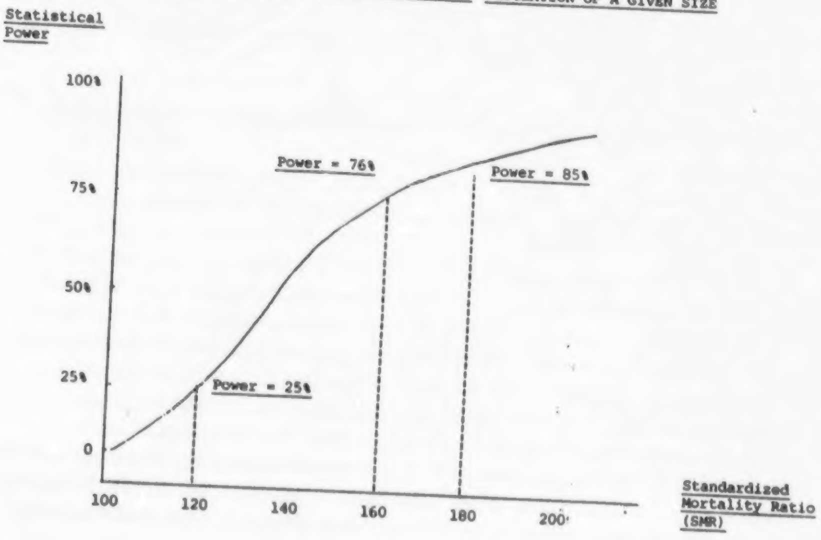


figure that would produce an SMR of 150). The second distribution illustrates the fact that even if the study group were subjected to an SMR of 150, one might not expect to observe exactly 30 deaths. This is the case because natural sampling variability might produce a different number. On the basis of our critical value of 28.8, an observed number of deaths of 28 (or fewer) would not be regarded as statistically significant. On the other hand, an observed figure of 29 deaths (or more) would produce a significant outcome, and would be deemed to identify the risk correctly. The probability that our study could produce statistically significant results is referred to as the power of the study. This percentage is obtained (see Figure 7) by measuring the area of the second distribution curve that falls to the right of the critical value. In our example, this figure has been calculated as 59 per cent. This means that for a study of this size, there is a 59 per cent chance that a true SMR of 150 could be detected.

Statistical power tends to increase when either a) large cohort populations are studied and/or b) pronounced SMRs are present. The power of a study with a fixed cohort size to detect SMRs of varying magnitudes may be illustrated graphically through the use of a power curve (see Figure 8). As will be seen, the senstivity of a study increases markedly as higher SMRs are encountered.

A further issue to resolve is the level of statistical power that will be judged adequate for a particular study. In broad terms, a study must be

Figure 8: AN EXAMPLE OF A POWER CURVE FOR A COHORT POPULATION OF A GIVEN SIZE



sensitive enough to detect a real risk in an environment that may contain many causal factors. The U.S. Occupational Safety and Health Administration (OSHA), in an attempt to deal with the issue of study sensitivity, has developed a number of criteria to gauge when a non-positive test result obtained in a study will be taken as evidence of no risk.[15] These criteria, which are made applicable to studies that examine the effects on mortality caused by exposure to suspected carcinogens, may be summarized as follows:

a) The subjects investigated in the study must have had at least 20 years of exposure to the agent under examination.
b) Thirty or more years of observation must have elapsed since initial exposure to the agent.
c) The study must demonstrate adequate power to detect a 50 per cent increase in cancer incidence at any site where the agent is judged likely to act in humans.

Although OSHA does not define what level of statistical power would be deemed acceptable, most epidemiologists employ the 80 per cent figure as the lower limit of adequacy. This level would be obtained where the expected number of deaths for a specific cause in a study group is 29 or more.

e) Risk Gradient

The hypothesis that worker exposure to an environmental agent is associated with a particular disease will become more persuasive where it can be shown that the risk of contracting the disease varies with the degree of exposure to the agent. This sort of relationship between exposure and a disease outcome is referred to as a risk gradient. In order to determine whether such a gradient in fact exists, two factors must be considered. These are:

i) The method employed to quantify the exposures received by individual workers (the dose metric).
ii) The mathematical model used to relate exposures to the onset of particular disease outcomes (the dose-response model).

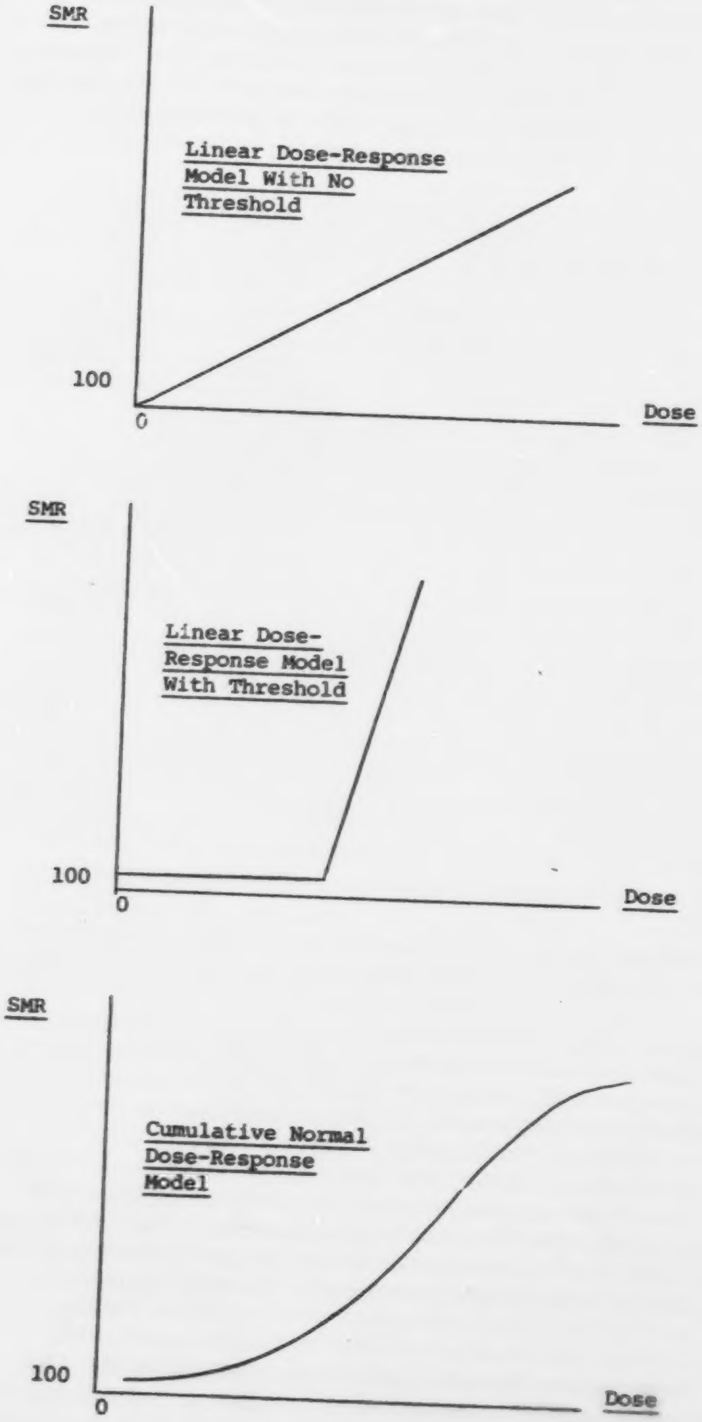
The standard method utilized to measure a worker's exposure to an agent over time is simply to multiply the number of months or years that an individual worked with the agent by the dose received in each period. The figure obtained is referred to as cumulative intake. In some situations, however, where the effects produced by an agent may depend on the pattern of exposure (e.g. short periods of exposure to high concentrations being more dangerous than long periods of exposure to lower doses), the calculation of the dose metric should ideally take other factors into account. It should be noted that the further back one goes in history, the more difficult it is to obtain accurate estimates of exposure.

Once the method for calculating cumulative intake has been settled upon, exposure and mortality data can be examined to determine whether a risk gradient is present. Where exposure data is both reliable and plentiful, the precise parameters of the risk gradient (graphically expressed as a dose-response curve) will become evident. A risk gradient may also, on occasion, be observed in those situations where the procedure utilized to calculate dose is relatively crude. In such a case, demonstrating that a risk gradient exists may help to rule out the hypothesis that excess mortality in a cohort is attributable to confounding factors. It should also be noted that the steeper the risk gradient, the stronger the evidence that exposure to an environmental agent is associated with the development of a disease.

Once exposure data have been related to the mortality experience of a cohort, the next step is to develop a dose-response model. Such a model will help researchers to calculate the risk of mortality that can be expected when workers are exposed over time to given levels of an agent. The three dose-response models most commonly utilized by epidemiologists are illustrated in Figure 9. The simplest dose-response model depicted in the diagram is represented by a linear (straight line) dose-response curve without threshold. In this model, the risk of dying from a particular disease (as measured by the SMR calculation) varies in direct proportion to the dose received. Furthermore, it is assumed that an exposure threshold (i.e. a level of exposure below which adverse health effects will be absent) does not exist. The middle diagram in Figure 9 depicts a linear dose-response model with threshold. In this model, it is assumed that excess mortality arising from exposure to an environmental agent will begin to occur only when a given dose level has been exceeded. The third dose-response model depicted in Figure 9 is referred to as the cumulative normal model. This model takes into account the fact that the susceptibility of individuals within a cohort to an environmental agent will follow a normal distribution. Thus, the slope of the curve rises gently at first (to take into account the low personal tolerances of some workers to the agent) then more sharply (to reflect the fact that the majority of workers with average tolerances will now be affected), and finally gently again (to take into account the above average tolerances exhibited by some workers to the agent).

The decision to choose one model over another depends largely on which curve best fits the observed data. In the situation where only high dose observations are available (a feature common to most occupational mortality studies), any of the competing models will appear suitable. In such cases, an epidemiologist may simply select the curve that he or she personally feels is most appropriate. Where some low dose observations are also present, the chances are greater that one model will be found to more adequately fit the data than others. In determining whether the appropriate dose-response model has been chosen, one should look for: i) an indication that the authors have considered the possibility that other models could be applied to the observed data, and ii) statistical evidence to indicate that the model chosen actually fits the data better than possible alternatives. Where such explanations are not provided or appear inadequate, one must consider the possibility that different dose-response models could also be applied to the data. Furthermore, any estimate of risk obtained through the use of the selected model must be interpreted with caution.

Figure 9: SOME COMMON DOSE- RESPONSE MODELS



f) Discussion of Possible Biases

When evaluating a historical prospective cohort study, one must consider as positive any honest effort made by the authors to discuss the methodological strengths and weaknesses of the study and, in particular, the likely size and direction of potential biases. For example, in those studies where the quality of exposure records is less than optimal, it would be useful if the authors presented risk estimates on the basis that exposures were i) calculated accurately, ii) overestimated, and iii) underestimated. In general, where a particular methodological procedure has not been mentioned explicitly in a study, one can assume that this feature has not been incorporated into the research.

b) The Evaluation of Proportional Mortality Studies

The proportional mortality study is the second class of research design that is typically encountered in the occupational health literature. As will be seen from a review of Table 2, which appears in the advisory memorandum, the seven criteria proposed for the evaluation of proportional mortality studies do not vary appreciably from those employed to assess the quality of historical prospective cohort studies. In fact, four of the criteria specified—the illustration of an exposure gradient, the allowance for latency effects, the basis for the choice of a control group, and classification of mortality data by age and calendar time of death—are virtually identical to the criteria that were discussed in the last portion of the appendix. The sections that follow will elaborate on each of the criteria set out in Table 2.

In assessing the quality of a proportional mortality study, a particularly important consideration is the process by which deceased workers in a study group are identified. As mentioned earlier in this appendix, information on the mortality experience of a working population is ordinarily obtained from company work and pension records (collectively referred to as benefits files). The quality of the information that may be derived from such records, however, tends to vary considerably. For example, in those companies where worker pension rights become vested after a relatively short period of service, employers will usually be aware of almost all the deaths that have occurred among present and former employees. However, in companies where pension rights do not vest for many years or where pension schemes are entirely absent, there is the risk that plant records will document only a small proportion of the deaths occurring among ex-employees. This problem will be accentuated in those industries where workplace populations tend to be particularly mobile.

Company records that are able to trace only those workers who have been employed in a plant for relatively long periods of time will ordinarily not be suitable for use in proportional mortality studies. That is the case because short and long-term employee groups could exhibit fairly distinct mortality patterns. The biases likely to arise by studying a sample weighted heavily in favour of long-term employees could be most pronounced where it is shown that occupational exposures forced some workers to leave a plant shortly after commencing employment.

In order to obtain more complete information on the mortality experience of study group members, an alternative approach is to analyse death certificates gathered from the geographic region surrounding the plant. For this technique to produce fairly complete data, however, two preconditions must be met:

i) The geographic region must possess a fairly stable population base.
ii) The job titles recorded on death certificates must be specific.

To further supplement the data contained in death certificates and company benefits files, one could attempt to trace the actual whereabouts of former employees. This added step is taken rarely, however, since proportional mortality studies are not designed to be exhaustive research efforts. In evaluating a proportional mortality study, it is therefore important for the reviewer to determine what efforts the author has taken to ensure that a very high percentage of study group deaths have been considered.

The second factor to take into account in judging the quality of a proportional mortality study is the method used to classify deaths. Ideally, the cause of death recorded for each worker should be taken directly from the employee's death certificate. Other sources of information on this subject (most notably, data gleaned from insurance claim forms) are less acceptable. A further point that must be considered is whether causes of death have been catalogued according to a recognized classification scheme. Ideally, deaths should be categorized to conform with the method employed by the national agency that stores vital statistics. Almost universally, the framework employed will be that of the 'International Classification of Disease Adapted'.[16] The reader should also attempt to determine whether competent personnel were chosen to assign deaths to one category or another.

The third methodological criterion set out in Table 2 deals with the basis for selecting a control group. As indicated earlier in this appendix, most proportional mortality studies employ an external control group, rather than an internal control, for the purpose of calculating the expected number of deaths for a study population. The external control group is typically made up of members of a national population group. Less frequently, however, a local population group may be employed for comparative purposes. The advantages and drawbacks inherent in each of these approaches has already been discussed in the section of the appendix dealing with the analysis of historical prospective cohort studies.

As a general rule, proportional mortality studies that employ internal control groups are judged to have a better methodological quality than studies that make use of an external control group. Depending on the size and other characteristics of a company's work force, the internal control group could be made up of in-plant workers who: i) have not been exposed to the environmental agent under investigation, or ii) have suffered only limited exposures. For a review of the benefits conferred by the use of an internal control group, the reader should refer to the section on historical prospective cohort studies noted above.

The three remaining evaluative criteria may be grouped under the category of statistical analysis. The initial requirement is that the mortality data presented in a study take into account the effects of age and calendar time of death. Ordinarily, this objective is accomplished by segregating persons who have died of particular diseases into different age brackets. The analysis is further refined by considering the distribution of deaths in an age category at the date when workers in this group actually died. Detailed information of this sort serves two purposes. First, the analysis of particular causes of death is made more specific. Second, the comparison of observed deaths to expected deaths, which are already sub-divided in this fashion, becomes more meaningful.

The fifth criterion set out in Table 2 requires that obvious sources of competing risk be taken into account when study results are evaluated. The meaning of this criterion can best be understood through the use of an example. Let us suppose that in a particular workplace i) the rate of fatal accidents is particularly high, and ii) employees are also exposed to an environmental agent that induces fibrotic lung disease. Let us hypothesize further that of the 110 deaths observed in this study population, 10 are due to fatal accidents and two are the result of fibrotic lung disease. Our final assumption will be that in the general population, 1.9 per cent of all deaths recorded are attributable to fibrotic lung disease. In order to compute the number of expected deaths from this cause in the sample group, one would perform the following calculation:

number of deaths expected in the study group from fibrotic lung	=	total number of deaths observed in the study group	X	proportion of deaths from this cause found in the general population
	=	110	X	.019
	=	2.09		

Since the number of deaths observed in the study group (two) is less than the number expected (2.09), one could conclude that an excess risk is not present for this cause of death. However, if the 10 deaths caused by accidents (a source of competing risk) are excluded from the analysis, the expected number of deaths will fall to 1.9 (100 x .019)*. On the basis of this result, there is some evidence to indicate that members of the study group are more apt to die of fibrotic lung disease than members of the general population. This could, in turn, suggest that a workplace agent is associated with this excess risk. The main point to bear in mind in this discussion is that when the expected number of deaths for a cohort group is obtained through proportional mortality calculations, one occupational risk encountered in the workplace may mask the presence of other risks. The proper course to take in such a situation is to exclude fatalities induced by the competing risk before calculating total observed deaths.

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*Technically, the proportion of deaths arising from fibrotic lung disease in the control population should also be recalculated after eliminating deaths attributable to workplace accidents. In the result, the expected number of deaths related to fibrotic lung disease for this group would increase slightly.

The next criterion to consider is the illustration of an exposure gradient. As a rule, the hypothesis that a group of workers faces an elevated risk of contracting a particular disease will be strengthened where it can be demonstrated that risk increases with exposure. Exposure can be quantified in fairly crude terms (e.g. according to duration) or more precisely (e.g. by measuring cumulative exposures to a particular agent). A more detailed discussion of this criterion may be found in the portion of the appendix that analyses historical prospective cohort studies.

The last criterion to consider is whether the study has addressed the question of latency. As indicated earlier in this paper, some occupational diseases are characterized by fairly long periods of sub-clinical development. In order to determine whether a disease with a prolonged latency period has, in fact, been induced by exposure to an environmental agent, one must know whether the disease has appeared in the anticipated time frame, relative to the date of first exposure. Information of this sort should ideally be supplied by sub-dividing members of the study group who have died of the particular disease, according to the length of time between first exposure and death. A fuller discussion of this criterion may be found in the section of the appendix referred to above.

3. CHARACTERISTICS OF THE DIFFERENT CLASSES OF OCCUPATIONAL MORBIDITY STUDIES

This segment of the appendix will briefly discuss the attributes of the five occupational morbidity study designs that are set out in Figure 2 of the advisory memorandum. It should be noted that three of the study designs depicted in this diagram: the randomized control trial, the case-control study and the case series study are virtually identical to the designs of similar namesake that are employed to conduct occupational mortality studies. The essential difference lies in the nature of the outcomes investigated.

a) Randomized Control Trials

The attributes of the randomized control trial have already been discussed in the section of the appendix dealing with occupational mortality studies. It is worth repeating, however, that while the RCT is not ordinarily encountered in the occupational health literature, this class of study design acts as a standard against which other study types are judged.

b) Longitudinal Studies

The distinguishing feature of a longitudinal study is that members of the cohort group under investigation are identified for research purposes at an early and uniform point in their exposure histories. A group of workers with this characteristic is referred to as an inception cohort, and may include individuals who were employed in a plant when it commenced operations and/or those who were hired subsequently. Longitudinal studies may either employ a true prspective design (i.e. a cohort of workers is followed forward in time from the date the study commences) or a historical prospective design (i.e. a cohort of workers is identified at some point in the past and followed through to the present). As has been indicated in the section of the appendix on occupational mortality studies, the true prospective design is subject to fewer sources of bias than the historical prospective approach.

In a longitudinal study, the incidence of disease among members of the study group is compared with that recorded for a control population. The members of the control group may either have limited occupational exposure to the agent under investigation or have no exposure at all. It would be unusual for a morbidity study to make use of an external control group for purposes of comparison since detailed information on disease incidence is ordinarily not available for the general population. External control groups might, however, be employed in studies of cancer incidence (as opposed to cancer mortality) and birth defects since, for these classes of disease, population based registries do exist. The procedures employed to test for the presence of disease will vary according to the outcome being studied. Once it is determined that the morbidity rate for the exposed group is higher than that documented for the control group, the next step is to link the information on morbidity with exposure data in order to establish a dose-response relationship.

The use of the longitudinal approach permits researchers to evaluate the morbidity experience of both present and former employees. The ability to assess the health status of ex-employees is judged to be particularly important since some workers may have left a worksite as a direct result of the health effects induced by exposure to an environmental agent. Should the disease history of these workers not be included in the analysis of study results, there is the distinct possibility that the risk associated with exposure to an agent may be underestimated.

c) Cross-Sectional Studies

The design of the typical cross-sectional study does not differ markedly from that of a longitudinal study, except that the exposed workers are not part of an inception cohort. Instead of including in a study all employees who have been exposed to an agent from the date of their arrival in a plant, the cross-sectional approach considers only those individuals who are employed in a worksite at a particular point in time. These employees are then asked about past exposures, and examined for the disease of interest. Although a cross-sectional study can be conducted more expeditiously and at lower cost than a comparable longitudinal study, this type of design is unable to assess the health of workers who have left a plant before the date of the survey. This methodological weakness could introduce a serious source of bias into study results, particularly where it is hypothesized that ex-employees may have left their jobs because of occupational exposures. It should be noted, in this respect, that longitudinal and cross-sectional studies conducted on the same working population may produce widely differing results.[17]

d) Case-Control Studies

The attributes of the case-control study have already been discussed in the portion of the appendix that deals with occupational mortality studies. As indicated in Figure 2 of the advisory memorandum, the evidence derived from a case-control study is judged to have less inherent quality than the results obtained from either a longitudinal or cross-sectional study. This conclusion is based on the fact that the case-control approach is susceptible to relatively more sources of bias than the other study designs. There is always the risk, for example, that a number of potential 'cases' may have died of the disease under investigation before being interviewed.[18] The case-control approach may also be less than optimal for use in the occupational morbidity field since the disease records that such studies utilize are typically scarce and of a poor quality.

e) Case Series Studies

The description of the case series study, which appears in the section of the appendix dealing with occupational mortality studies, applies equally to morbidity studies. Two important points should be re-emphasized, however. First, of all the study classes listed, the evidence obtained from a case series study has the lowest inherent quality. Second, although one should not ordinarily place much weight on the evidence derived from such studies (particularly when taken alone), the observations set out in these papers may provide the first suggestive link between exposure to an environmental agent and the onset of disease. Thus, such studies will often be useful in providing direction for more sophisticated epidemiological research.

4. CRITERIA FOR EVALUATING THE QUALITY OF OCCUPATIONAL MORBIDITY STUDIES

Table 3 of the advisory memorandum sets out a number of criteria that may be employed to assess the strengths and weaknesses of three classes of occupational morbidity studies - the randomized control trial, the longitudinal study and the cross-sectional study. As might be expected, many of the criteria used to evaluate mortality and morbidity studies are similar. This portion of the appendix will place emphasis on those criteria that have special relevance to morbidity outcomes, and suggest how each criterion could be satisfied. It should be noted that the first four criteria outlined in Table 3 are particularly important for evaluative purposes.

a) The Provision of an Inception Cohort

The most important criterion for judging the quality of an occupational morbidity study relates to the manner in which the cohort group is selected. A study that employs an inception cohort is judged to be methodologically superior to one that utilizes a cross-sectional approach. In this respect, the results obtained from a study with a cross-sectional design must be interpreted with caution.

b) The Clinical Validity of the Outcome Investigated

In conducting studies to assess the relationship between occupational exposures and subsequent morbidity, direct measures of disease outcome are rarely available. As a result, the approach normally taken is to assess a number of signs and symptoms that appear in the individuals studied. In most cases, the outcome investigated will not be entirely sensitive (i.e. always present when the disease is present) or specific (i.e. always absent when the disease is absent). Where the objective of a study is to provide guidance on the choice of a safe exposure level, scientists will typically measure the early signs of a disease that are thought to be the precursors of overt clinical disease. For example, one might assess changes in lung function and the occurrence of 'small round opacities' on chest X-rays as signs of fibrotic lung disease in hard-rock miners. Similarly, nerve conduction velocity, tremor and changes in peripheral vision might be used as measures of neuropathy (nervous system damage) in workers exposed to organic mercury. Finally, liver enzyme tests could be employed to assess liver damage in employees who work with solvents.

In assessing the quality of an occupational morbidity study, it is necessary to evaluate the clinical validity of the outcome that has been chosen for investigation. The reader must be satisfied that the outcome in question is justifiable on the basis of its overall sensitivity and specificity to a particular disease process, and that the authors of the study understand the etiology (causes) of the disease. The outcome should also be the product of a high quality diagnostic procedure (the so-called 'gold standard' in the field). In addition, where an early sign of a disease is selected for study, the natural history of the disease should be reviewed to determine whether the outcome selected is, in fact, relevant. A particular finding will ordinarily be regarded as clinically valid where it reflects the extent of morbidity in an accurate fashion.

c) The Reliability of the Measure of Outcome

Given that the outcome chosen for study makes clinical sense, one must then determine whether the result can be assessed in a reliable fashion. Objective outcomes, which depend neither on the subjective perceptions of study participants nor on the judgments of assessors, tend to be more reliable than results that require some degree of subjective interpretation. The reliability of objective outcomes will be enhanced where these can be quantified in a numerical fashion. The reader must be wary, however, that the desire to develop objective outcomes has not compromised the clinical validity of the indices chosen. For example, while computer analysed electro-encephalograph traces may produce a plethora of highly quantified and reproducible measurements, these may bear little relationship to the presence or absence in workers of the clinical signs of chronic mercury poisoning.

Studies that utilize subjective outcomes should be assessed on the basis of the reliability of the methods employed to ascertain the extent of disease. The reliability of most subjective assessments can be improved by breaking observed results down into smaller components. After each component is evaluated, a cumulative score or categorization can be obtained. Another approach, which has been employed in the diagnosis of fibrotic lung disease, involves the dissemination of a standard set of X-ray films that depict progressive gradations in disease severity. The use of these films increases the reliability of the diagnoses obtained. The degree of confidence that one can have in a subjective measure of outcome will also be enhanced where the authors of a study are able to demonstrate that assessors i) interpreted test results in a consistent fashion when these were reviewed on subsequent occasions, and ii) agreed among themselves with respect to the classification of a disease outcome. Readers should, in addition, search the body of a study for statements on i) the qualifications and/or training of the assessors in relation to the disease being investigated, and ii) the procedures that were followed when assessors could not agree on the classification of outcomes. A particular finding will ordinarily be regarded as reliable where it accurately reflects the extent of morbidity, and is not unduly influenced by errors of measurement.

d) Strategy Taken to Ensure a Blind Assessment of Outcome

In judging the quality of an occupational morbidity study, it is important to ascertain whether there has been a blind assessment of examination and test results. An assessment will be catagorized as blind where the investigator knows nothing of a subject's previous disease or exposure history. In some cases (e.g. where one is searching for a general or systems effect associated with exposure to an environmental agent), assessors might also be blinded with respect to i) the type of disease being investigated, and ii) the results that study organizers hope to achieve.

Blind assessments are necessary in order to ensure that neither conscious nor unconscious biases have influenced the interpretation of study results. It has been shown, for example, that persons who interpret diagnostic specimens may have their judgments influenced drastically by prior knowledge of the clinical features of a case.[19] Furthermore, where a subject exhibits a sign or symptom that is presumed to be important, a clinician may carry out more frequent or more detailed searches for the outcome of interest.[20] It is therefore important for the reviewer to search the methods section of a morbidity paper to ascertain whether assessors were properly blinded. Where a statement to this effect is absent, one can ordinarily assume that the proper procedures have not been followed.

e) The Extent to Which All Cohort Members Were Recruited

It is also important that occupational morbidity studies attain high rates of cohort participation. This is the case because subjects who choose not to take part in research projects may do so because they fear that an occupational disease will be detected. For this reason, it is essential that the rates of participation attained in a study be fully discussed. As a general rule, a participation rate of at least 80 per cent is required before a study's results will be regarded as credible. A rate of 95 per cent or better will be considered excellent.

f) Criteria for Inclusion/Exclusion

It is also important to evaluate the criteria that a study employs for determining which workers should be included in (or excluded from) a cohort group. This issue becomes particularly important in those situations where some members of a study population exhibit signs and symptoms that could be associated with exposure to a workplace agent, but that also might arise because of i) exposure to another environmental factor, or ii) the presence of a separate disease. For example, among workers employed in the chlor-alkali industry, tremor of the limbs could be induced not only by occupational exposure to inorganic mercury, but also as a result of Parkinson's disease or alcoholism. While it is attractive to contemplate excluding workers with a history of either co-morbidity or exposure to a confounding factor from such studies, researchers are rarely able to attribute, with precision, signs or symptoms to a particular causal agent. Therefore, rather than not considering workers with conditions that mimic the outcome of interest, a safer tactic is to document the occurrence of the co-morbidity or the confounding factor, and then analyse subjects with or without the trait or factor separately. The object of this exercise is to determine whether exposure to the environmental agent produces similar risk gradients in both groups of workers. For example, in conducting a study on the relationship between exposure to solvents and the incidence of bladder cancer, one would not eliminate smokers, but examine smokers and non-smokers as separate strata in the same analysis. If one is confident, however, that a disease outcome in a worker is attributable to a non-occupational factor, then the individual should be excluded from the study. It should also be emphasized that the inclusion or exclusion criteria that are adopted for the study cohort must be applied to the control group as well.

g) The Length of the Follow-up Period

In selecting an appropriate period of follow-up, the objective is to ensure that cohort members are observed well beyond the point in time when an occupational disease might be expected to arise. What will constitute a sufficient follow-up period will depend on the nature of the disease being investigated. Where a disease is progressive (e.g. asbestosis), a lengthy period of follow-up may be required in order to identify successive stages of the disease. Where a disease is not progressive, however, or where outcomes are reversible, a shorter follow-up period will ordinarily be sufficient. As indicated earlier in this appendix, studies investigating the incidence of cancer in the workplace should incorporate a follow-up period of at least 30 years.

In the context of occupational morbidity studies, a follow-up rate of 90 per cent will generally be regarded as satisfactory.[21] Where the rate of follow-up is less complete, serious concerns must be raised about the extent to which the disease patterns observed in those workers who are traced accurately reflect the experience of the entire cohort. High rates of follow-up are particularly important in those situations where it is necessary to examine workers on successive occasions to chart the progress of a disease (rather than only once when the cohort is first recruited).

h) The Basis for Comparison

In an occupational morbidity study, it is preferable that the control group selected for examination consists of workers who have not been exposed to the agent under investigation. This is normally accomplished by drawing members of the control group from a separate industry. In some morbidity studies, however, the control group is made up of workers who are employed in the same plant or industry as members of the exposed cohort. Although the latter approach may be questionable in those circumstances where it is difficult to assess the degree of exposure that members of the control group have actually suffered, the selection of a comparison group from the same plant or industry will ordinarily provide a better match between cohort and control group members.

i) Other Criteria Broadly Applicable to All Classes of Epidemiological Studies

The criteria that have been described under the previous nine subheadings bear particular relevance to occupational morbidity studies, which are generally subject to more sources of bias than occupational mortality studies. There are, however, a number of criteria that are broadly applicable to both classes of studies. These criteria are: the size of the cohort, the amount of detail in work history files, the extent and quality of industrial hygiene data, the consideration of confounding factors, the quality of the follow-up technique, the use of appropriate statistics and the discussion of possible biases. For a detailed review of these criteria, the reader is invited to consult the portion of the appendix on occupational mortality studies.

5. A FRAMEWORK FOR DETERMINING WHETHER THE ASSOCIATIONS REVEALED IN EPIDEMIOLOGICAL STUDIES ARE CAUSAL IN NATURE

Table 4, which appears in the advisory memorandum, sets out a number of criteria for determining whether an association revealed in an epidemiological study is causal in nature. This portion of the appendix will elaborate on each of the criteria listed in the Table. Note that the criteria are discussed in the order of their importance.

a) Evidence Obtained From True Experiments in Humans (i.e. from Randomized Control Trials)

Data obtained from a randomized control trial represents the highest quality evidence from which to establish causal relationships between exposure to an environmental agent and the incidence of disease. However, as indicated earlier in this paper, it is usually not possible, in an occupational setting, to randomly allocate groups of workers to receive or to not receive exposures. Therefore, although one should seek data from randomized control trials to demonstrate causation, it will also be necessary to judge the quality of evidence obtained from other classes of study designs.

b) The Strength of the Association

The strength of the association between two variables may provide important evidence on the question of causation. Where an association is found to be strong, it is less likely that the relationship was induced by a confounding factor or arose due to chance alone. It should be emphasized, however, that a finding of statistical significance between two variables may not be sufficient, in and of itself, to demonstrate causation. Similarly, one should not necessarily dismiss a cause and effect hypothesis on the basis that a study has revealed only a slight association between two variables. The key question to consider is whether the results obtained are clinically significant. That is to say, the differences between observed and expected outcomes must be large enough to be unusual, and the results should not have arisen because of defects in study design. It should also be noted that researchers will ordinarily place the greatest degree of weight on the associations obtained from study designs that are higher up in the scale of quality.

c) Consistency of the Association from Study to Study

The criterion of consistency will be satisfied where an association between exposure to an environmental agent and the incidence of a disease is revealed, on a repetitive basis, by different researchers utilizing various study approaches. Consistency of results lends credence to the hypothesis that the agent under investigation has caused or, at least, contributed to the disease of interest. In a similar fashion, confidence in a negative study result will be enhanced where several research projects have failed to demonstrate a relationship between exposure and the disease outcome.

d) Demonstration of the Correct Temporal Relationship

This criterion has been alluded to in previous discussions on the question of latency. Essentially, the temporality test will be fulfilled where it can be shown that a correct sequence of exposure events has preceded the development of a disease. In some cases, this diagnostic test will be fairly easy to apply. For diseases with extended latency periods, however, it is often difficult to demonstrate that the symptoms have appeared in the anticipated time frame, relative to date of first exposure. It should be noted that the criterion of temporality is one test that is particularly useful for ruling out causation.

e) The Existence of a Dose-Response Gradient

This diagnostic test will be satisfied where it can be shown that within a study population the risk of contracting a disease varies according to the level of exposure that workers receive. Although the existence of such a dose-response gradient will support the hypothesis that an environmental agent has caused the occurrence of a particular disease, the gradient will not necessarily prove causation. That is the case because the form of a dose-response gradient could be influenced by such confounding factors as age and the presence of other disease causing agents. In a similar fashion, the absence of a dose-response gradient is not necessarily synonymous with the absence of risk. Researchers may fail to detect a gradient for a variety of reasons, most of which are tied to the poor quality of study data. For example: i) subjects may be placed in the wrong categories, ii) the range of doses considered may be too narrow to exhibit a dose-response gradient, and iii) the effects of exposure on susceptible workers may be masked where these individuals constitute a minority of the study population.

f) The Criterion of Epidemiologic Sense

An association will be said to make epidemiologic sense where it accords with current understanding about the distribution of disease rates across populations that have different levels of exposure to the suspected causal factor.

g) The Criterion of Biologic Sense

For this criterion to be satisfied, it must be shown that the association revealed in a study can be explained on the basis of a known biological or physical mechanism or that a similar causal nexus (between exposure and disease) has been found in other animal species. Since many associations are biologically plausible (on the basis of the contradictory facts that often appear in the scientific literature) it is important that researchers pay particular attention to those biologic observations that are judged to be most significant.

h) The Specificity of the Association

An association will be described as specific where it can be shown that a disease outcome was induced by one environmental factor alone. Since most diseases are brought about by the interplay of many contributing factors, the criterion of specificity will usually not be satisfied.

i) The Criterion of Analogy

This criterion, which is regarded as the least important diagnostic test listed in Table 4, would come into play where a causal relationship is identified that has an affinity to the association that is being investigated. One could then argue by analogy that, since one has seen a similar type of relationship elsewhere, the causal connection could also exist in the case under review. For example, the application of this criterion would suggest a link between the incidence of scrotal cancer among chimney sweeps and the appearance of lung cancer in coke oven workers.[22]

It should be noted that a formal scoring system could be developed to assess the impact that each of the nine criteria has on the question of causation.[23] The task force felt, however, that the adoption of such a mechanism was not essential, provided that the criteria set out in Table 4 are applied in a consistent fashion.

Footnotes

1. McMichael, A. J., Standardized Mortality Ratios and the 'Healthy Worker Effect'—Scratching Beneath the Surface. In: Journal of Occupational Medicine, vol. 18, no. 3, March, 1976, p. 165.
2. Advisory Council on Occupational Health and Occupational Safety, Report of the Special Advisory Committee on Carcinogens. In: Fourth Annual Report, April 1, 1981 to March 31, 1982, p. 172.
3. These criteria have been adapted from Roberts, R., Methodological Review and Summary of Epidemiological Studies of Asbestos Exposure—Mortality Studies with Environmental Data, April, 1982.
4. Address to the task force by N. Lockington of DOFASCO Inc., June 2, 1982.
5. Smith, T., Chronic Cadmium Exposures Associated with Kidney Function Effects. In: American Journal of Industrial Medicine, vol. 1, 1980, p. 333.
6. Lockington, N., *op. cit.*
7. List provided by Dr. M. Nazar, Chief, Occupational Health Laboratory, Ontario Ministry of Labour, in an address to the task force, June 2, 1982.
8. Swedish Plastics and Chemicals Suppliers Association (PKL), Limit Values, Translation of the Ordinance AFS 1981:8. Issued by the Swedish National Board of Occupational Safety and Health, p. 44.
9. Austin, M. A., *et al*, Methods for Determining Long-term Survival in a Population Based Study. In: American Journal of Epidemiology, vol. 110, 1979, p. 747.
10. Shannon, H., Categorization of Statements on Asbestos Related Diseases. Paper submitted to the Canadian Centre on Occupational Health and Safety, May 11, 1982, p. 8.
11. McMichael, A. J., *op. cit.*, p. 165.
12. *Ibid.*, p. 165.
13. Gilbert, E. S., Some Confounding Factors in the Study of Mortality and Occupational Exposures. In: American Journal of Epidemiology, vol. 116, no. 1, July, 1982, p. 178.
14. See generally S. Hernberg, Negative Results in Cohort Studies—How to Recognize Fallacies. In: Scandinavian Journal of Work, Environment and Health, supp. 4, vol. 7, 1981, p. 121.
15. U.S. Occupational Safety and Health Administration, Identification, Classification and Regulation of Potential Occupational Carcinogens. In: Federal Register, vol. 45, no. 15, book 2, January 22, 1980, p. 5059.
16. U.S. Department of Health, Education, and Welfare, Public Health Service, National Centre for Health Statistics, Eighth Revision International Classification of Diseases Adapted for Use in the United States, 1968. This publication is based on the Eighth Revision of the International Classification of Disease, developed by the World Health Organization.
17. As an example, in a cross-sectional study on a cohort of employees who worked in a British asbestos factory, it was estimated that one per cent of those exposed would have crepitations after a cumulative asbestos dose of 112 fibre years/cm^3 (British Occupational Hygiene Society, Hygiene Standards for Chrysotile Asbestos Dust. In: Annals of Occupational Hygiene, vol. 11, 1968, p. 51). However, in a subsequent study conducted in the same workplace, it was estimated that a one per cent prevalence of crepitations could occur at cumulative exposure

levels that were considerably lower (43 fibre years/cm^3). One reason for this fairly large difference is that the second study made the effort to assess the health status of some workers who had previously left the factory (G. Berry *et al.*, Asbestosis: A Study of Dose-Response Relationships in an Asbestos Textile Factory. In: British Journal of Industrial Medicine, vol. 36, 1979, p. 105).

18. Sackett, D., A Review of Diagnostic Tests for Causation. Paper prepared for the Ontario Royal Commission on Asbestos, Dec. 12, 1980, p. 2.
19. Department of Clinical Epidemiology and Biostatistics, McMaster University Health Centre, How to Read Clinical Journals: III To Learn the Clinical Course and Prognosis of Disease. In: CMA Journal, vol. 124, April 1, 1981, p. 871.
20. *Ibid.*, p. 871.
21. *Ibid.*, p. 871.
22. Sackett, D., *op. cit.*, p. 9.
23. For an example of such a scoring system, see *ibid.*, p. 16.

Glossary

A Priori Hypotheses Relationships between environmental factors and the onset of particular types of disease, whose existence might be predicted on the basis of previous studies, or biologic understanding.

Case-Control Study A research design wherein individuals who have contracted a disease (the cases) are matched to another group that is free of the disease under consideration (the controls). The two groups are then traced backwards in time to compare the degree of exposure that members of each group have had to the suspected disease causing agent.

Case Series Study A work that describes the characteristics of a group of patients who are suffering from a particular disease. Typically, these individuals will have attended one medical practitioner or a clinic, and their health status will be described according to possible causative exposures or risk factors.

Clinical Validity of a Finding A particular finding will ordinarily be regarded as clinically valid where it reflects the extent of morbidity in an accurate fashion.

Cohort A group of persons who share a common experience within a defined time period.

Confidence Intervals A statistical computation that permits one to ascertain the range within which the real SMR might be expected to fall given a) a cohort group of a given size, b) a known number of observed and expected deaths, and c) a specified level of statistical confidence.

Confounding Factor A variable that ordinarily a) has a causal relationship with the outcome of interest, and b) is distributed unequally among members of the exposed and non-exposed study groups.

Control A group of persons with whom the exposed cohort is compared.

Cross-Sectional Study A research design that considers only those individuals who are employed in a worksite at a particular point in time.

Dose The amount of a substance that an exposed individual is actually absorbing.

Epidemiology The science that endeavours to assess the distribution of diseases in human populations and the causes or determinants of these diseases.

External Control Group A control group composed of individuals from a national or local population.

Follow-up Procedure The method employed to determine whether subjects are alive or dead at the end of a study or whether they have contracted a non-fatal disease.

Historical Prospective Cohort Study A research design that resembles that of the prospective cohort study except that instead of following individuals forward in time for many years in order to gauge the effects that exposures may have on mortality, a cohort of workers is identified at some point in the past and then followed through to the present.

Inception Cohort A cohort group whose members include individuals who were employed in a plant when it commenced operations and/or those who were hired subsequently.

Internal Control Group A control group composed of individuals who work in the same plant as the cohort, but who have either not been exposed to the agent under investigation or suffered only limited exposures.

Latency Period The often lengthy time period that precedes the clinical manifestation of some diseases.

Longitudinal Study A research design that follows workers forward in time from initial exposure in order to record the occurrence of disease.

Power of a Study A statistical computation that measures the likelihood that a study of a given size within a population that exhibits a real underlying risk will be able to detect a statistically significant risk in the cohort group.

Proportional Mortality Ratio The ratio of the number of deaths observed in a study group over the number of deaths that would be expected. This figure measures the magnitude of risk for different causes of death in proportional mortality studies.

Proportional Mortality Study A research design wherein one computes the total number of deaths observed in an occupational group, classifies these deaths according to cause, and then compares the figures obtained with the number of deaths that would be expected for the same causes in the general population.

Prospective Cohort Study A research design wherein individuals who have been exposed to an environmental agent are followed forward in time in order to gauge the effects that such exposures have on mortality.

Randomized Control Trial A research design wherein individuals are randomly allocated to either a) receive or b) not receive exposure to a particular environmental agent. Both the exposed and non-exposed groups are then followed forward in time to monitor the incidence of a particular disease outcome.

Reliability of a Finding A particular finding will ordinarily be regarded as reliable where it is not unduly influenced by errors of measurement.

Risk Gradient A relationship between exposure and a disease outcome that describes the risk of contracting the disease for varying degrees of exposure to an agent.

Standardized Mortality Ratio (SMR) The ratio of observed deaths in a cohort divided by the number of deaths that would normally be expected in a group with a similar age distribution. This statistic, which takes into account man-years at risk, is the measure most often employed to evaluate mortality in prospective cohort type studies.

Tests of Statistical Significance Tests that endeavour to determine whether the number of deaths observed in a cohort (expressed as 'O') is unusually in excess of the number of deaths expected (expressed as 'E').

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May 10, 1983

Dr. J.F. Mustard
Chairman
Advisory Council on Occupational
Health and Occupational Safety
15th floor
400 University Avenue
Toronto, Ontario.
M7A 1T7

Dear Dr. Mustard:

On April 8, 1983 you transmitted a copy of the Appendix to Council's Advisory Memorandum 82-V concerning principles for analyses of epidemiological studies in the field of occupational health and safety. Since that date, this detailed and well reasoned Appendix has been under study by my officials. I will forward a final reply to the Council's advice on this important issue within the near future.

Please extend my thanks to Council members and Task Force members who worked so diligently on this memorandum.

Yours sincerely,

R.H. Ramsay
Minister

Advisory Memorandum 82-VI

Ontario
Advisory Council on
Occupational Health &
Occupational Safety

Office
of the
Chairman

400 University Avenue
Toronto, Ontario
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416/965-2446

February 25, 1983

The Hon. R. H. Ramsay
Minister of Labour
400 University Avenue
Toronto, Ontario
M7A 1T7

Dear Mr. Minister:

On behalf of the Advisory Council, I am enclosing Advisory Memorandum 82-VI in which council has reviewed the radiation spectrum associated with visual display units and the possible reproductive hazards associated with working on, or near, these devices.

This memorandum represents part one of council's deliberations into the possible health hazards of visual display units. Part two of the report will deal with the ergonomic issues.

Yours truly,

J. F. Mustard, M.D.
Chairman

Encl.

c.c. T. E. Armstrong, Q.C.
Dr. A. E. Robinson

Advisory Memorandum 82-VI to the Minister of Labour
February 25, 1983.

Interim Recommendations on the Electromagnetic Spectrum and the Potential Reproductive Hazards of Visual Display Units

Possible Health Hazards of Visual Display Units: Part I

INTRODUCTION

The far-reaching implications of the rapid and widespread introduction of microtechnology into almost every sector of the workplace have been hotly, and often bitterly, debated on all sides. The advisory council, through its Task Force on the Possible Health Hazards of Visual Display Units, has been considering these implications and, in this interim report, has focused its concern on the radiation spectrum associated with video display units (VDUs) and on the possible reproductive hazards associated with working with these devices.

A. ELECTROMAGNETIC RADIATION

Basically, the video display unit operates in a similar way to a television set. It contains a source of electrons and a phosphor-coated screen (anode) within a specially designed vacuum tube (the cathode ray tube [CRT]). Under high voltage, electrons are emitted by the electron gun (cathode) and accelerated towards the anode. The beam scans the screen at a predetermined rate and projects electrons according to an electronically-induced signal. When the electrons interact with the phosphor coating of the screen, visible radiation is produced and an image is formed.[1]

For many years, there has been an awareness that video devices can emit X-rays when certain physical and electronic conditions are met. More recently, however, this concern has extended to include large portions of the entire electromagnetic (EM) spectrum. The spectrum of natural EM radiations runs from gamma rays, with frequencies of 10^{25} Hz and wavelengths of 10^{-14} metres, through the X-ray, ultraviolet (UV), visible, infrared (R), microwave and radio frequency (RF) regions to low frequency and extremely low frequency radiation (ELF) with frequencies below 300 Hz and wavelengths of 10^{6} metres. While these regions are not sharply delineated, it is convenient to divide them according to the nature of the physical and biological effects produced, i.e. as ionizing and non-ionizing radiation.

Ionizing Radiation

Ionizing radiation is that portion of the EM spectrum having sufficient energy to cause a neutral atom or molecule to acquire a positive or negative charge. The dividing line between ionizing and non-ionizing radiation is situated in the far ultraviolet region of the spectrum. The source of ionizing radiation in the VDU is the interaction of the electron beam of the tube with a target. Weak X-ray emissions are produced by secondary emission through the interaction of the electron beam, accelerated by the high voltage of the cathode ray tube, and the phosphor-coated screen. Because of the low energy of these X-rays, virtually all the emissions that are directed towards the operator are absorbed by the material of the screen or by the housing of the unit.

A number of surveys have been conducted in recent years dealing with the exposure dose from X-rays emitted by VDUs produced by various manufacturers.[2] With few exceptions, it was found that emission levels from the units tested, both under normal and worst-case conditions, fell well below the current Canadian[3] and U.S. emission standards. The total number of machines that have been tested, however, represent only a small fraction of the VDUs currently in use in North America, and the possibility exists that there are machines which, due to malfunction or manufacturing defect, emit X-radiation in excess of current standards. The effects of ionizing radiation on biological organisms have been extensively documented for several decades. Based on the existing scientific evidence, it is unlikely that X-ray emissions from VDUs present any measurable health hazard to the operator or to the fetus in the case of a pregnant woman.[4] Given, however, that there is a continuous dose-response relationship between absorbed radiation and biological effect, any exposure produces some degree of increased risk, and although this risk decreases as the intensity of the radiation diminishes, no definite threshold dose has been established.

The emphasis in the quality control of the production of VDUs tends to be performance rather than health and safety oriented. The advisory council feels, therefore, that additional surveillance is needed, particularly with respect to the possible emission of ionizing radiation from the sets.

ACOHOS RECOMMENDATION 82-4

> that the Minister of Labour consult with the legal branch of the ministry to determine whether the provincial government has jurisdiction to require that the following two recommendations be enacted.

ACOHOS RECOMMENDATION 82-5

> that the Minister of Labour require increased surveillance of video display units for ionizing radiation both at the point of manufacture and during the life of the equipment, and that this surveillance be carried out in accordance with a test protocol to be developed by a technical committee appointed from nominees of management and labour. The results of the first year of testing should be reviewed by the committee, and recommendations for future testing should be made to government.

ACOHOS RECOMMENDATION 82-6

> that the Minister of Labour require that VDUs, including those brought into the province for sale, should be labelled to indicate compliance with the test protocol.

ACOHOS RECOMMENDATION 82-7

> in the event that the implementation of these recommendations is *ultra*

vires the province, that the Ministry of Labour work with the appropriate agencies to encourage implementation at the federal level.

Non-ionizing Radiation

Non-ionizing radiation is characterized by frequencies below the far ultraviolet region of the EM spectrum and includes ultraviolet (UV), visible light, infrared (IR), microwave and radio frequency (RF) radiation. These non-ionizing radiations produce a variety of biological effects that are not necessarily harmful and that depend upon the frequency and intensity of the radiation. For example, in the visible light portion of the spectrum, human visual response is dependent on a minimum intensity of radiation. Other portions of the EM non-ionizing radiation spectrum are associated with a variety of biological effects, some of which are well established while others are still the subject of controversy.

All of the radiation surveys completed to date support the conclusion that emission levels from VDUs in the UV, visible and IF regions are several orders of magnitude below the recommended occupational health limits.[5]

Depending on the design of the machine and upon environmental conditions such as the humidity of the workplace, there is the potential for high charges of static electricity to build up on the sets, causing microshocks to the operator. Static charges have also been linked by some researchers to the occurrence of skin rashes amongst VDU workers.[6]

The radio frequency band of the EM spectrum extends from a few Hz to approximately 10^9 Hz. The likelihood that this type of radiation is emitted from any electronic device depends upon the operating characteristics of the electronic components and circuits, particularly the oscillator circuits. In the case of VDUs, the major source of RF emission is the flyback transformer, which is the high voltage source within the machine. While there is, at present, no scientific evidence to link reported health effects among human populations to exposure to RF fields generated by VDUs,[7] there are gaps and inconsistencies in our knowledge in this area, particularly in relation to the possible health effects of electrostatic fields, extremely low frequency electric fields and very low frequency modulated radio frequency fields.[8]

In addition to any potential health effects, RF fields are also of concern since they can cause interference with radio communications and with the operation of other electronic equipment. Finally, the high voltages present on components such as the flyback transformer make shielding of such components important for safety reasons. Therefore, to reduce electromagnetic interference, to promote safe servicing of VDUs and to reduce the possible health risks to the operator, the advisory council makes the following recommendation:

ACOHOS RECOMMENDATION 82-8

that the Ministry of Labour work with other interested government agencies to require manufacturers of VDUs to provide electrical shielding of each unit as a whole, and of the flyback transformer in particular.

> The type and placement of the shielding should be determined by a technical committee set up in a similar manner to that proposed in ACOHOS Recommendation 82-5.

B. POTENTIAL HEALTH HAZARDS ASSOCIATED WITH VDUs

Since the widespread introduction of VDUs into the workplace, there have been an increasing number of reports of a variety of health problems among operators of the machines. VDU workers have complained of eyestrain, blurred vision, fatigue, insomnia, headaches, tension, nausea, irritability, depression, and sore necks, backs and legs.[9] There have also been more isolated reports alleging serious permanent injury, in particular the clusters of birth defects and miscarriages widely reported in the North American media amongst women who have worked with, or in the vicinity of, VDUs during part, or all, of their pregnancy. Because of the considerable concern generated by these reports of possible reproductive hazards associated with working with VDUs, the advisory council felt that it should give priority to this issue.

Potential Reproductive Hazards

At the present time, only two of the approximately 10 reported clusters of miscarriages and/or birth defects amongst VDU operators have been subject to critical appraisal using epidemiological techniques.[10] While both found the increased incidence of adverse pregnancy outcomes in the subject group compared to that of the control population to be statistically significant, neither study could establish causality between reproductive outcome and time spent working on, or near, a VDU. Since apparent clusters of adverse pregnancy outcomes will be observed to occur by chance if many groups of women are subject to passive surveillance, the reported clusters are difficult to interpret. All that can be said at the present is that there is an insufficient data base to establish whether the clusters are attributable to VDU exposure or to some confounding variable. Therefore, given the current scientific uncertainty, a full scale epidemiological investigation into the possible reproductive effects of VDUs is called for.

Council recognizes that, should ACOHOS Recommendations 82-10 and 82-11 be fully implemented, it will be extremely difficult to conduct prospective epidemiological studies within the jurisdictions in which these recommendations are applied. This fact does not preclude retrospective epidemiological studies on populations that have already been exposed to VDUs. Such studies are not without difficulties, however, particularly those problems associated with the retrospective collection of accurate exposure and outcome data. Suitably designed animal experimentation will therefore be necessary, particularly in the area of the potential effects of electromagnetic radiation on the reproductive period.

ACOHOS RECOMMENDATION 82-9

> that the Minister of Labour support, as a matter of urgency, well-designed epidemiological and animal studies to investigate the possible association of working with VDUs and abnormal reproductive function. Such a study should be carried out by a well-qualified epidemiological

team working with a steering committee made up of representatives from management, labour, government and members of the scientific community.

In view of recent studies raising the possibility of exposure to PCBs and strong electrostatic fields among VDU operators, these factors should be included in the concerns of the epidemiological study. This will require field testing in selected locations.

Since the questions surrounding the potential reproductive hazards of VDUs cannot be answered on the basis of existing scientific evidence, the reported clusters, and the very significant concern such reports have generated, cannot be dismissed lightly. If further investigation should demonstrate that a quantifiable risk to pregnant operators does, in fact, exist, the magnitude of the resulting problem could be enormous. Therefore, until such time as the current uncertainty is resolved, a precautionary approach should be taken.

Council, in its deliberations of this complex subject, was faced with the dilemma of trying to resolve a genuinely held concern about a specific health effect of VDUs with inadequate evidence to satisfactorily resolve this concern. One course of action that has been adopted to resolve this dilemma in both the private and public sectors (including the Ontario Government), has been to offer a pregnant VDU operator the option of a transfer to alternative work within the employer's organization for the duration of her pregnancy. If an alternative position is available, a temporary transfer may be offered with rate retention as, for example, by Air Canada and the Globe and Mail, or at a lower wage level if the only available alternative position is a lower paying one as, for example, by Bell Canada. In other workplaces, however, the only option offered to a pregnant worker is to either work with a VDU or leave the job.

If the recognition of the concerns of pregnant VDU operators is to be treated equitably in a system where some areas of both the private and public sectors already have arrangements for transferring such workers to suitable alternative work, it seems fair that all pregnant VDU operators should be given the same opportunity. Council therefore makes the following recommendations:

ACOHOS RECOMMENDATION 82-10

> that until such time as the current uncertainty is resolved, the Minister of Labour require employers to offer alternative work, if available, within their organizations to pregnant VDU operators, without financial penalty or loss of benefits to the employee. This course of action should be reviewed in the light of the findings resulting from the implementation of ACOHOS Recommendation 82-9.

Where suitable alternative work is not available for the pregnant operator who requests a transfer, a situation that is more likely to occur in smaller workplaces, then for the sake of equity, compensation should be made available for those workers who still do not wish to operate a VDU. In the absence of a comprehensive compensation scheme for pregnant workers who work in situations or with agents that are likely to harm the fetus, the two most logical alternatives are Unemployment Insurance Compensation and Workers' Compensation benefits.

Although the Workers' Compensation scheme was originally formulated to compensate workers physically injured in the workplace, the scope of its coverage is continually being expanded to include other work-related conditions. Currently, pursuant to the code for medical surveillance under the Ministry of Labour's lead regulation, a woman capable of bearing children must be removed from lead exposure when her blood lead concentration is found to exceed 0.40 mg/L in order to safeguard the developing fetus. Under section 16(2) of the regulation, such a removal would then entitle the woman to compensation for loss in the manner and to the extent provided by the *Workers' Compensation Act*. Even though there is uncertainty about whether such a blood lead concentration would be harmful to the fetus, the provision is intended as a preventive measure and enables female workers to be removed from the workplace before there are indications of clinical illness. This principle is further extended in the current Quebec health and safety legislation, which entitles a woman who is pregnant or who is breast-feeding her infant to Workers' Compensation benefits if she is exposed to a pregnancy hazard and if suitable alternative work is not available. These considerations, together with the fact that the workers' compensation scheme is under provincial jurisdiction, would seem to make it the most practical interim solution to the question of compensation.

In order not to impose an economic penalty on the small employer, and to discourage possible discrimination against women of childbearing age, suitable funding could be taken from either general tax revenues or from a general industrial levy. Council is of the opinion that the protection of pregnant women and their unborn children is a collective, social responsibility, the major cost of which should be borne by society as a whole.

Council further recognizes that unless full compensation is offered to pregnant operators who cannot transfer to alternative work, a situation may be created in which a woman must choose between earning a full salary by exposing her unborn child to risk and suffering an economic loss. To avoid creating a financial incentive to expose the fetus to possible harm, council recommends that the pregnant VDU worker be entitled to full compensation without loss of employment benefits if no other work is available.

ACOHOS RECOMMENDATION 82-11

> that the Minister of Labour consult with the Workers' Compensation Board and other government agencies to establish arrangements that would ensure that where alternative work is not available within the employer's organization, a pregnant VDU operator will receive full compensation without financial penalty or loss of benefits.

Future Considerations

The question of the possible reproductive effects of VDUs and the concern that this question has generated in the workplace reflects the complex problems involved in introducing a new technology into society. It has been predicted that the impact, both positive and negative, of microelectronic technology on workers in the next few years will far exceed that of any previous technological innovation. While the huge potential gains in efficiency and productivity must be recognized, the human aspects, including the potential health effects, cannot be ignored. Management, labour and government must remain sensitive to the concerns and needs of workers caught in this evolution and encourage their active participation and co-operation in engineering out the potential hazards as technological changes are introduced.

This advisory memorandum represents the completion of Part One of council's deliberations into the possible health hazards associated with working with VDUs. Part Two of the report will consider the ergonomic issues, including the possible health effects of equipment design and layout, lighting, organization of work time and job content.

Footnotes

1. For an introduction to the design and operational characteristics of VDUs, see Cakir, A., Hart, A.J. and Stewart, T.M. Visual Display Terminals, Wiley— Interscience Publication, 1980.
2. Moss, C.E., *et al*. A report on electromagnetic radiation surveys of video display terminals. DHEW (NIOSH) Publication, no. 78-129. Cincinnati: NIOSH 1978. Weiss, M.M. and Peterson, R.C. Electromagnetic Radiation Emitted from Video Display Terminals. American Industrial Hygiene Association Journal, v. 30, No. 8, August 1978 p. 357-362. Wolbarsht, M.L., *et al*. Electromagnetic emission from visual display units: a non-hazard. In: Ocular Effects of Non-Ionizing Radiation. Bellingham: Society of Photo-Optical Instrumentation Engineers, 1980. Terrana, T., *et al*. Electromagnetic radiations emitted by visual display units. In: Grandjean, E. and Vigliani, E. Ergonomic Aspects of Visual Display Units. London: Taylor and Francis, 1980. Murray, W.E., *et al*. A radiation and industrial hygiene survey of video display operations. In: Select Research Reports on Health Issues in Video Display Terminal Operations. Cincinnati: NIOSH, 1981. An Evaluation of Radiation Emission from Video Display Terminals. HHS Publication FDA 81-8153, Bureau of Radiologic Health, U.S. Department of Health and Human Services, 1980.
3. Maximum Radiation Levels from the *Radiation Emitting Devices Act*, Revised Statutes of Canada 1970. ch. 34 (1st supp.)

Type of Radiation	*Standard*
Ionizing Radiation	0.5 millirem per hour
Ultraviolet	1 milliwatt/cm^2
Infrared	10 milliwatt/cm^2
Radio Frequency	1 milliwatt/cm^2

4. For a general review of the literature dealing with the effects of ionizing radiation on the developing embryo and fetus, see Hoffman, D.A., Fetten R.P. and Cyr, W.H. Effects of Ionizing Radiation on the Developing Embryo and Fetus: A Review, HHS Publications (FDA) 81-8170 (August 1981).
5. See note 2 above.
6. Rycroft, R.J.C. and Calnan, C.D. Facial rashes among visual display unit operators, in HSAT Research Group Papers Presented at a One Day Conference, Health Hazards of VDUs? on Thursday, December 11, 1980 at Loughborough University of Technology, Loughborough: HSUT Research Group, 1980.

7. Stuchly, M.A., Repacholi, M.H., Lecuyer, D.W. and Mann, R.O. Radiofrequency Emissions from Video Display Terminals. Health Physics, (in press). Stuchly, M.A., et al. Extremely Low Frequency Electromagnetic Emissions from Video Display Terminals and Other Devices. Health Physics, (in press).
8. Marha, Karel. The State of Knowledge Concerning Radiation Emissions from Video Display Terminals. Paper presented at Science Focus, Ottawa, October 6, 1982.
9. See, *inter alia*, Murray, W.E., et al. Potential Health Hazards of Video Display Terminals. DHHS (NIOSH) Publication No. 81-129 U.S. Department of Health and Human Services, Cincinnati, June 1981. DeMatteo, R. The Hazards of VDTs, Ontario Public Service Employees' Union, 1981. Purdham, J.T. A Review of the Literature on Health Hazards of Video Display Terminals. Canadian Centre for Occupational Health and Safety, Hamilton, 1980. Rosenbaum, Linda. Health Effects of Video Display Terminals: The Non-Radiation Problems. Department of Public Health: Toronto, 1981.
10. (a) The August, 1980 study of a cluster of spontaneous abortions at the Sears Roebuck and Company Southwest Regional Headquarters in Dallas, Texas by the Center for Disease Control in Atlanta. Eight of 12 pregnancies in which conception occurred between May 1979 and June 1980 among VDU workers in the regional headquarters office resulted in spontaneous abortion or neonatal death.
    (b) The 1980 study of three cases of congenital malformation and seven cases of miscarriage among pregnant VDU workers at Defense Contract Administration Services Region, Atlanta, conducted by the U.S. Army Environmental Hygiene Agency.

Acknowledgements

The membership of the Task Force on the Possible Health Hazards of Visual Display Units included one member of the advisory council, Dr. G. J. Stopps, Department of Preventative Medicine and Biostatistics, University of Toronto, (chairman), and Mr. Robert DeMatteo, Occupational Health and Safety Representative, Ontario Public Service Employees Union, Dr. Stephen Garnett, Department of Nuclear Medicine, McMaster University, Dr. Elizabeth Kaegi,* Medical Director, C-I-L Incorporated, Ms. Jennifer Keene-Moore, Design Interpretive, Bell Northern Research, Dr. John Parker, Department of Opthalmology, University of Toronto, Dr. James Purdham, Director of Technical Services, Canadian Centre for Occupational Health and Safety, Professor Robin Roberts, Department of Epidemiology, McMaster University Medical Centre, Dr. Stan Stuchly, Department of Electrical Engineering, University of Ottawa, and Ms. Linda Torney, Local Representative, Southern Ontario Newspaper Guild.

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* Appointed to Council, November 1, 1982

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March 9, 1983

J. Fraser Mustard, M.D.,
Chairman,
Advisory Council on Occupational
Health and Occupational Safety
15th Floor
400 University Avenue
Toronto, Ontario

Dear Dr. Mustard:

On March 1, 1983 I received a copy of Advisory Memorandum 82-VI containing interim recommendations on certain issues related to visual display units (VDUs) . I wish to thank Council members and members of the task force who prepared the report for their efforts and I look forward to receiving further advice on the ergonomic aspects of the design and use of VDUs. To facilitate the review by the Ministry, I would ask whether any support documents developed by or for the task force as a basis for its deliberations could be made available to my officials.

So far, only a preliminary review of the memorandum has been completed. I noted with interest Council's finding that, "the effects of ionizing radiation on biological organisms have been extensively documented for several decades. Based on existing scientific evidence, it is unlikely that x-ray emissions from VDUs present any measurable health hazard to the operator or to the fetus in the case of a pregnant woman." This conclusion seems to me to be important to the further consideration of the implications of your advice.

In the days to come my officials will further review with their federal counterparts your comments with respect to manufacturing standards, quality control testing and other procedures performed on VDUs before they enter the market place. They will consult again with federal and provincial officials in respect of the current knowledge of the nature and extent of radiation emitted by VDUs in the light of your memorandum. In addition, they will consider the need for shielding to reduce electrical and/or magnetic fields.

After these consultations have been completed I should be in a position to respond specifically to your recommendations concerning the need to test VDUs on a routine basis and to determine whether some additional shielding is necessary.

Council has referred to the public concern about the health hazards associated with VDUs. It has highlighted the question of the possible effects of the operation of VDUs on fetal development and the need for further research. My officials concur with Council's recommendation and agree that an epidemiological study devoted to this question would be difficult to carry out. Nonetheless, there are initiatives under consideration within Ontario and at the federal level which suggest that a health status study of VDU operators, such as the survey carried out by the Canadian Labour Congress, may be a feasible and useful undertaking. I shall provide more concrete details about these initiatives as soon as possible.

Pending the availability of results of definitive studies, Council recommends that the Ministry adopt a "precautionary approach" in dealing with pregnant VDU operators. In order to properly assess Council's specific proposals, further clarification of recommendations 82-10 and 82-11 would be helpful. In particular, I would appreciate receiving comment on the following questions:

- In recommendation 82-10 Council suggests that the Minister require employers to provide alternative work to pregnant VDU operators. Does Council mean that the Minister should mandate this by law, or does Council mean that employers should be urged to adopt this practice to alleviate employee apprehensions?

- In recommendation 82-11, does Council intend that consideration be given as to whether existing legislation provides the basis for compensating VDU operators where suitable alternative work cannot be found for them, or does Council intend that new legislation providing for such compensation be enacted; further, does Council envisage that any such considerations should include the broader issue of whether and if so, how a compensation scheme could be developed and implemented, given that it is not possible to determine conclusively that employee health may be at risk.

There is no doubt that the introduction of advanced technology into the workplace raises fundamentally important issues. Your Council quite rightly has emphasised that the regulation of toxic substances should be based on the firmest scientific evidence. The Advisory Memorandum 82-VI highlights the problem that arises when the introduction of a new technology gives rise to health concerns that are not, apparently, based upon clear scientific evidence. I would appreciate Council's considered advice as to how this broader issue can best be approached, not only in the context of VDUs, but in the broader context of emerging advanced technology in the workplace.

My officials would be pleased to meet with Council to consider the implications of these questions if you believe it would assist in your deliberations. I look forward to receiving your comments.

Yours sincerely,

R. H. Ramsay,
Minister.

Ontario

Advisory Council on
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Occupational Safety

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416/965-2448

May 10, 1983

The Honourable R. H. Ramsay
Minister of Labour
400 University Avenue
14th Floor
Toronto, Ontario
M7A 1T7

Dear Mr. Minister:

Thank you for your prompt response of March 9, 1983 to Advisory Memorandum 82-VI in which you requested clarification of recommendations 82-10 and 82-11.

The word 'require' in recommendation 82-10 is imperative and is used in this way throughout the memorandum. Council's intent is to recommend that the ministry introduce a mandatory requirement that employers offer alternative work, if available, within their organizations, to pregnant VDU operators for the duration of their pregnancies. Since the option of transfer is already available to VDU operators in many large organizations both private and public, for the sake of equity it should be made available to all pregnant operators. As council stated in its memorandum, this would be reviewable in the light of both the implementation of ACOHOS recommendations 82-4 to 82-9 and future technological changes.

Members wished to avoid creating a financial incentive to exposing a fetus to possible harm, and recognized that placing an additional financial burden on a woman during pregnancy can have adverse effects on her child. It follows logically, therefore, that a pregnant worker who cannot transfer to suitable alternative employment should be entitled to full compensation for the duration of her pregnancy. Council recognizes that the question of financial compensation for a pregnant worker is a complex one that may ultimately be part of an overall maternity leave policy.

Regarding the implementation of recommendation 82-11, however, council was of the opinion that, given the ministry's greater expertise in translating matters of principle into clear and concise legislation, the formulation of the specific details relating to the implementation of both recommendations 82-10 and 82-11 should be left with the ministry, and it is anxious that the ministry retain a fair degree of flexibility in this regard.

..../2

The issue of the potential reproductive hazards associated with working with VDUs has been a difficult one for council and one which has underscored the importance of addressing all potential health risks associated with a new technology prior to its introduction into the workplace. It also raises a complex question of equity as between workers in large and small workplaces, which recommendation 82-10 attempts to address. The matter of equity as between VDU workers and workers exposed to potential and known reproductive hazards from other sources is part of this issue of women in the workplace and will be addressed in the Advisory Memorandum on Women and Reproductive Hazards in the Workplace.

I hope that this addresses your concerns adequately. Should you wish further clarification, do not hesitate to let me know.

Yours truly,

J. F. Mustard, M.D.
Chairman

cc to: T. E. Armstrong, Q.C.
Dr. A. E. Robinson

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May 12, 1983.

J. Fraser Mustard, M.D.,
Chairman,
Advisory Council on Occupational Health
and Occupational Safety,
15th floor,
400 University Avenue,
Toronto, Ontario,
M7A 1T7.

Dear Dr. Mustard:

Thank you for your letter of May 10 responding to my request for clarification of recommendations 82-10 and 82-11 contained in Memorandum 82-VI.

Your letter indicates, in clear language, that Council's intention was to recommend that the Ministry introduce a mandatory requirement that employers offer alternative work, if available, within their organizations, to pregnant VDU operators for the duration of their pregnancies. I take the phrase "mandatory requirement" to be equivalent to a statutory obligation.

These recommendations, as well as the others contained in the Memorandum, will be carefully assessed by the Ministry's staff. However, I am still unclear on a matter which seems to be of fundamental importance.

In Dr. Elgie's letter to you dated April 23, 1981, he invited Council to form a "technical committee to review the evidence pertaining to the various implications for health associated with the use of the video display terminals." This request was made, as Dr. Elgie observed, due to the fact that "some workers using these terminals and their employers continue to doubt the safety of working with video display terminals, especially where a pregnant woman is involved." Your letter of May 10 is helpful, as far as it goes, but I am still unclear as to whether the recommendations contained in Council's Advisory Memorandum are premised on a positive finding that VDTs are injurious to the health of pregnant employees, to the fetus, or to both. Until a definitive reply is provided to this threshhold question, it is difficult for me to assess the various policy options to which Council has referred.

Please accept my assurance that I have no wish to prolong this exchange of correspondence with Council. However, I know you will appreciate the reason for this further and, I would hope, final request for advice, on a matter of fundamental importance in our consideration of this important issue. In preparing your response, you might address one additional point that I raised in my letter of March 9: namely, whether there are any supporting documents developed by or for the task force which might be of assistance to my officials in their deliberations.

I appreciate Council's co-operation in this difficult assignment.

Yours sincerely,

R. H. Ramsay,
Minister.

Note
This letter was received too late for council to prepare a reply for inclusion in this year's annual report.

Advisory Memorandum 82-VII

Ontario

Advisory Council on
Occupational Health &
Occupational Safety

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416/965-2448

March 17, 1983

The Honourable R. H. Ramsay
Minister of Labour
400 University Avenue
14th Floor
TORONTO, Ontario.

Dear Mr. Minister:

On behalf of the Advisory Council, I am enclosing Advisory Memorandum 82-VII in which council has made a number of recommendations concerning the legal interpretation of the Occupational Health and Safety Act.

This memorandum represents only a part of council's deliberations into the implementation of the Act and further recommendations will be forthcoming as council continues its consideration of this important area.

Yours truly,

J. F. Mustard, M.D.
Chairman

cc to: T. E. Armstrong, Q.C.
Dr. A. E. Robinson

Advisory Memorandum 82-VII
to the Minister of Labour
March 17, 1983

Concerning the Legal Interpretation of the Occupational Health and Safety Act

INTRODUCTION

Statutory interpretation is, generally speaking, the role of judicial and semi-judicial bodies, and is usually performed in the context of a dispute between parties that involves a specific set of facts or circumstances. Thus, provisions of the *Occupational Health and Safety Act* may be interpreted by the courts pursuant to a prosecution under section 37 of the Act and by the Ontario Labour Relations Board or a board of labour arbitrators under section 24. Since the legislation is still relatively new, however, the case law is limited. Consequently, the ministry is, of necessity, required to offer guidance on the interpretation of the statute to assist its inspectors and other operational personnel in the application and administration of the legislation. Although the ministry's guidelines have no binding legal status, they function as working interpretations of the Act until subject to formal legal challenge. These guidelines therefore constitute a major source of interpretive material regarding the *Occupational Health and Safety Act*.

The advisory council recognizes that the area of occupational health and safety is a dynamic one; one which is evolving, and which will continue to evolve, over time. In examining the legal interpretation of the Act, with particular emphasis on the right of a worker to refuse unsafe work, council is of the opinion that, given the potential impact of the ministry's legal guidelines on the day-to-day application of the legislation in the workplace, any guidelines for the interpretation of the statute formulated by the ministry's legal branch should be broad and flexible enough to encompass future developments and changes of attitude.

THE RIGHT TO REFUSE UNSAFE WORK

The objective of the *Occupational Health and Safety Act* is the protection of workers' health and safety by way of the internal responsibility philosophy. The codification and expansion of the common law right to refuse to perform hazardous work has been a significant step towards giving workers more responsibility for their own health and safety and for that of other workers.

Sub-section 23(3) of the Act states:

> (3) A worker may refuse to work or do particular work where he has reason to believe that,
>
> (a) any equipment, machine, device or thing he is to use or operate is likely to endanger himself or another worker;
> (b) the physical condition of the work place or the part thereof in which he works or is to work is likely to endanger himself; or

(c) any equipment, machine, device or thing he is to use or operate or the physical condition of the work place or the part thereof in which he works or is to work is in contravention of this Act or the regulations and such contravention is likely to endanger himself or another worker.

It is the opinion of the advisory council that, given the history and purpose of the statutory right of workers to refuse to perform unsafe work, the ministry's interpretation of the 'right to refuse' provisions of the Act is too narrow and legalistic and not in keeping with the broad spirit of the legislation. In particular, the ministry's stated guideline that a *person* cannot be considered unsafe or a danger to other employees, and, therefore, that the presence of such an individual on the job site does not constitute grounds for a refusal to work under sub-section 23(3), is considered to be too restrictive. Fellow workers may present a potential hazard both to themselves and others because of their incompetence, inexperience, fatigue or the influence of alcohol or drugs, or because of a temporary physical disability that may interfere with the safe performance of their duties. It is argued, therefore, that the activities of such a worker are an integral aspect of 'the physical condition of the work place' pursuant to sub-section 23(3)(b) and, therefore, constitute grounds for a refusal to work by other employees who are likely to be endangered therein by these activities.

ACOHOS RECOMMENDATION 82-12

> that the Minister of Labour take appropriate steps to ensure that the interpretation of sub-section 23(3) of the Act is broadened to include the right of workers to refuse to work because they feel that they are endangered by hazardous situations created by fellow employees.

Confusion has been expressed in the workplace on the question of whether maintenance workers are afforded the right to refuse unsafe work under sub-section 23(3). A narrow reading of the words 'equipment . . . he is to use or operate' might result in maintenance workers being excluded from this provision. For greater certainty, therefore, council recommends a clarification of the interpretation of these words so that they will include the maintenance and repair of equipment. A similar clarification is needed regarding the words 'to use or operate' as set out in sub-section 17(2)(b) of the Act.

ACOHOS RECOMMENDATION 82-13

> that the Minister of Labour take appropriate steps to ensure that the interpretation of sub-sections 17(2)(b) and 23(3) of the Act is clarified to ensure that all individuals involved in the authorized maintenance and repair of any equipment, device or thing, be included in the ambit of these provisions.

Sub-section 17(2)(b) states that no worker shall use or operate any equipment, machine, device or thing or work in a manner that may endanger himself or any other worker.

This provision is derived from section 31 of the now repealed *Industrial Safety Act, 1971*, which states:

(1) Where a person has cause to believe that a machine, device or thing in or about an industrial establishment is unsafe that person shall not use or operate the machine, device or thing or cause or permit that machine, device or thing to be used or operated.

(2) If any machine, device or thing in or about an industrial establishment is in contravention of this Act or the regulations no person shall use or operate or cause or permit it to be used or operated.

(3) No person shall use or operate any machine, device or thing in or about an industrial establishment in a manner that does not comply with this Act or the regulations.

This section was the precursor of the 'right to refuse' as set out in sections 2 and 3 of the *Employees' Health and Safety Act, 1976*, which, in turn, was the basis of section 23 of the current statute. Given the similarity between sub-section 31(1)(c) of the 1971 Act and sub-section 17(2)(b) of the *Occupational Health and Safety Act,* there is a strong argument that sub-section 17(2)(b) also places a positive duty on the worker to refuse to work or operate equipment in situations that are likely to create a danger to himself or others. This interpretation would cover a number of potentially hazardous situations that do not currently fit within the criteria set out in sub-sections 23(3)(a), (b) or (c), for example:

- The situation in which an individual feels unwell, but who, because of poor labour/management relations or because of the lack of an adequate procedure in the workplace for dealing with sick workers, is required to work or to carry out specific tasks that he feels he cannot perform safely;
- The situation in which a worker with a physical or mental disability is suddenly required to perform a specific task that he feels he is incapable of performing safely, e.g. the claustrophobic worker who is required to work in a confined space. This situation must be contrasted with those in which the task in question is a condition of employment;
- The situation in which an inexperienced or untrained worker is required to use or operate equipment that he feels he is incompetent to work with;
- The situation in which a worker suffering extreme fatigue from, for example, working a double shift, is required to continue to perform his duties.

Any worker placed in these situations would be likely to operate equipment or work 'in a manner that may endanger himself or any other worker', and, therefore, would be under a legal duty to cease working until such time as he felt that he could continue to work safely. Council is of the opinion that, for greater certainty, the ministry should clarify its interpretation of section 17(2)(b) to ensure that workers who, because of a physical or mental condition, feel that they may create a hazardous situation by working, have the right to cease working until they feel that they can continue to work safely.

ACOHOS RECOMMENDATION 82-14

> that the Minister of Labour take appropriate steps to ensure that the interpretation of sub-section 17(2)(b) of the Act is clarified to create an obligation on the part of a worker to refuse to work if he believes that by using or operating his equipment, or by working, he would create a hazardous situation for himself or others.

THE MINISTRY'S ROLE IN THE INTERPRETATION OF THE ACT

The advisory council notes that it is the usual practice in government for ministries to formulate guidelines to aid in the interpretation of their enabling legislation in the absence of judicial or semi-judicial rulings, and that, without such an ongoing process, it would be difficult, if not impossible, for a ministry to administer a statute. It is felt, however, that much of the confusion and uncertainty regarding the interpretation of the *Occupational Health and Safety Act* could be eliminated if the ministry's legal guidelines were more widely circulated to both labour and management, and were routinely updated as new situations arose that required the ministry's legal assistance. Council is of the opinion that the ministry is not utilizing the current information channels to their fullest advantage in distributing this information.

ACOHOS RECOMMENDATION 82-15

> that the Minister of Labour take steps to ensure that the ministry's legal guidelines, together with periodic updates, enjoy wide distribution throughout the workplace. One possible mechanism to achieve this objective could be through the issuance of information bulletins to all joint health and safety committees. The process could be further facilitated by the circulation of guidelines used by inspectors in the performance of their duties.

FUTURE CONSIDERATIONS

Since the legislation is still relatively new, council feels that it would be premature to recommend clarification in many instances. However, further recommendations may be forthcoming in the future as the advisory council continues its deliberations into the legal interpretation of the Act.

Acknowledgements

The membership of the Task Force on the Implementation of the *Occupational Health and Safety Act* included the following members of the advisory council: Dr. J. F. Mustard, (chairperson), Dr. A. D. Wolfson (who served as chairman until his resignation from the task force on July 21st, 1982), Mr. W. A. Barnes, Mr. R. T. Boldt, Mr. J. Duffy, Mr. P. A. Fisher, Mr. J. Gill, Dr. E. Kaegi, Mr. M. A. Taschereau and Mr. E. A. Waddell. Members of the task force not on council were: Mr. K. Glassco, (Energy and Chemical Workers Union), Mr. J. N. Lockington, (DOFASCO), Mr. T. H. Meagher, (Ontario Federation of Labour), Professor R. Prichard, (University of Toronto), Mr. C. Schmidt, (United Rubber Workers of America) and Professor K. Swinton, (University of Toronto).

This advisory memorandum is based on recommendations made to the task force by its Sub-committee on Legal Interpretations. Membership of the sub-committee included the following members of the task force: Professor K. Swinton, (chairperson), Mr. J. Gill, Dr. E. Kaegi and Mr. J. N. Lockington.

Ontario

Office of the
Minister

Ministry
of
Labour

400 University Avenue
Toronto, Ontario
M7A 1T7
(416) 965-4101

May 4, 1983

J.F. Mustard, M.D.
Chairman
Advisory Council on Occupational
Health and Occupational Safety
15th floor
400 University Avenue
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

I write to thank you for submitting Council's Advisory Memorandum 82-VII concerning legal interpretations under the Occupational Health and Safety Act. The advice raises several complex questions which my officials have under study. The issue of the distribution of the Ministry's interpretations of the Act has been raised by labour representatives, and, at a meeting of your Council on March 8, attended by members of my staff, by Mr. Barnes of General Motors. More recently, the Report of the NDP Task Force on Occupational Health and Safety which was read into the record of the proceedings of the House on April 26 by the NDP House Leader, Mr. Martel, addressed the question.

Once my officials have completed their review of Council's report, I will provide a detailed response to Council's recommendations. Please thank the Council members for their diligent effort in preparing this Advisory Memorandum for my consideration.

Yours sincerely,

R.H. Ramsay,
Minister.

ADMINISTRATION

Legal Mandate of The Advisory Council

Section 10, the Occupational Health and Safety Act.

Advisory Council on Occupational Health and Occupational Safety
10.—(1) There shall be a council to be known as the Advisory Council on Occupational Health and Occupational Safety composed of not fewer than twelve and not more than twenty members appointed by the Lieutenant Governor in Council on the recommendation of the minister.

Term of office of members
2) The members of the advisory council shall be appointed for such term as the Lieutenant Governor in Council determines and shall be representative of management, labour and technical or professional persons and the public who are concerned with and have knowledge of occupational health and occupational safety.

Chairman and vice-chairman
3) The Lieutenant Governor in Council shall designate a chairman and a vice-chairman of the advisory council from among the members appointed.

Vacancies
4) The Lieutenant Governor in Council may fill any vacancy that occurs in the membership of the advisory council.

Remuneration and expenses
5) The remuneration and expenses of the members of the advisory council shall be determined by the Lieutenant Governor in Council and shall be paid out of the moneys appropriated therefor by the legislature.

Powers of advisory council
6) The advisory council, with the approval of the minister, may make rules and pass resolutions governing its procedure, including the calling of meetings, the establishment of a quorum, and the conduct of meetings.

Idem
7) The function of the advisory council is and it has power,
a) to make recommendations to the minister relating to programs of the ministry in occupational health and occupational safety; and
b) to advise the minister on matters relating to occupational health and occupational safety which may be brought to its attention or be referred to it.

Annual report
8) The advisory council shall file with the minister not later than the 1st day of June in each year an annual report upon the affairs of the advisory council.

Idem
9) The minister shall submit the report to the Lieutenant Governor in Council who shall cause the report to be laid before the assembly if it is in session or, if not, at the next ensuing session. 1978, c. 83, s. 10.

Primary objective of advisory council

To advise the Minister of Labour on all matters relative to occupational health and safety in Ontario.

Secondary objectives of advisory council

1. To ensure as far as is possible that the policies and programs in occupational health and safety effectively minimize the risks to health and safety in all workplaces in Ontario.
2. To ensure as far as is possible that knowledge about occupational health and safety is available to management, labour and the public and that it is understood by them.
3. To assist in promoting and establishing mechanisms involving management and labour to solve problems in occupational health and safety.
4. To ensure as far as is possible that there is appropriate manpower training and development for the occupational health and safety field.
5.* To review periodically the effectiveness of the policies and programs implemented to achieve secondary objectives 1 to 4.

Terms of reference of advisory council

1. To make recommendations on matters referred to it by the minister, submitted to it by interested parties or pursued by the council on its own initiative.
2. To advise the minister on programs in the field of occupational health and safety.
3. To advise the minister on policies, principles and procedures used in standard setting and in the development of guidelines to be used by the government.
4. To review and make recommendations to the minister on the introduction of new substances such as chemicals into the workplace.
5. To review and make recommendations on the detection, measurement and control of occupational health and safety hazards in the workplace.
6. To review and make recommendations about the arrangements for occupational health and safety for groups and areas where there are no formal health and safety programs or the programs are judged to be inadequate.
7. To advise the minister on priorities for research and development in occupational health and safety.
8. To advise the minister on priorities for manpower training and development in the field of occupational health and safety.
9. To prepare an annual report to the minister, which shall include the advisory memoranda, recommendations of the council and the government response.

*added June 1980

Meetings of The Advisory Council

April 13, 1982
May 11, 1982
June 8, 1982*
August 17, 1982
September 14, 1982
October 19,1982
November 30, 1982
January 12, 1983
February 8, 1983
March 8, 1983

Special Meetings of Council

January 11, 1983 — Presentation oral briefs re: council's *Discussion Paper on the Control of Workplace Carcinogens.*

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* **Discussions with deputy minister and staff followed by dinner meeting with minister.**

TASK FORCES

TASK FORCES OF ADVISORY COUNCIL ON OCCUPATIONAL HEALTH AND OCCUPATIONAL SAFETY

TASK FORCE ON PRINCIPLES AND PROCEDURES FOR SETTING STANDARDS AND REGULATIONS

Terms of Reference
To establish guidelines by which the council can determine the appropriateness of the principles, policies and procedures used in setting the standards and regulations in occupational health and safety in Ontario. To include such things as the development of the regulations and public input about those regulations.

Membership
L. Heard—Chairman
E. Mastromatteo *
J.M. More
R. Wilson *

Special Advisors for Regulations on

Vinyl Chloride	*Coke Oven Emissions*	*Asbestos*	*Noise*	*Isocyanates*
M. Farber — U of T	D. McCalla — McMaster U.	W.K. Morgan — Western U. H. Shannon — McMaster U.	P.W. Alberti — Mount Sinai Hospital W.A. Barnes — G.M. N. Caldbick, Chairman, Task Force on Noise J.W. Charters — Stelco	R.T. Boldt — Dow Chemical E. Kaegi — CIL D. McCalla — McMaster U.
Meetings Held				
Meeting in previous fiscal year	April 21, 1982 May 13, 1982**	June 1, 1982*** June 4, 1982**	Dec. 1, 1982 Dec. 8, 1982** Jan. 4 1983**	Jan. 24, 1983*** Jan. 28, 1983** Feb. 22, 1983***
Reports to Council				
Mar. 9, 1982	April 13, 1982 May 11, 1982 June 8, 1982	June 8, 1982 Sept. 14, 1982	Nov. 30, 1982 Jan. 12, 1983	Feb. 8, 1983 Mar. 8, 1983
Resulting in				
Advisory Memo 82-I April 20, 1982	Advisory Memo 82-II June 21, 1982	Advisory Memo 82-III July 12, 1982	Advisory Memo 82-IV Jan. 21, 1983	

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* resigned October 31, 1982
** with Ministry Staff
*** telephone conference

TASK FORCE ON LITERACY AND OCCUPATIONAL HEALTH AND SAFETY

Terms of Reference

i) To examine the extent of the problem of illiteracy in the workforce.
ii) To identify the effects of illiteracy on the effectiveness of occupational health and safety.
iii) To propose recommendations on how problems associated with illiteracy and occupational health and safety can be resolved in the short term and the long term.

Members

Council Members
W.A. Barnes
P.A. Fisher
E.A. Waddell — Acting Chairman from January, 1982 to June 1982

Others
James Draper — OISE — Chairman
R.J. Adams — McMaster University
J. Pearpoint — Frontier College
G. Wilson — UAW

Liaison Representatives
D. Maudsley — Ministry of Education
S. Pratt — Ministry of Citizenship and Culture

Meetings Held
April 28, 1982
June 11, 1982
December 16, 1982
January 17, 1983
January 31, 1983
March 7, 1983

TASK FORCE ON WOMEN AND OCCUPATIONAL HEALTH AND SAFETY

Terms of Reference

i) To review the occupational health and safety problems of women at work.
ii) To examine the issue of susceptibility.
iii To examine whether existing occupational health and safety standards and procedures take into account special needs, if any, of women.
iv) To propose recommendations to the council on any matters identified in the study.

Members

Council Members
G.J. Stopps — Chairman
N. Caldbick
J.M. More

Others
S. Bobier — Ortho Pharmaceutical (Canada) Ltd.
R. DeMatteo — Ontario Public Service Employees' Union

Meetings Held	*Reports to Council*
October 18, 1982	October 19, 1982
November 29, 1982	November 30, 1982
January 26, 1983	February 8, 1983
February 1, 1983	March 8, 1983

TASK FORCE ON THE ROLE OF HEALTH SURVEILLANCE AND HEALTH SCREENING IN OCCUPATIONAL HEALTH PROGRAMS

Terms of Reference

i) To identify the risks, benefits and costs of health surveillance and health screening in occupational health programs.
ii) To review the laws and procedures governing health surveillance and health screening with regard to the rights and duties of employers, employees, government and the professions.
iii) To make recommendations to the council on policies and principles governing health surveillance and health screening in occupational health programs.

Members

Council Members
A.D. Wolfson — Chairman (to July 22, 1982)
J.F. Mustard — Chairman (from July 23, 1982)
J.W. Charters
J.M. More
E. Mastromatteo (to October 31, 1982)

Others
S. Acheson — OFL (resigned February 1982)
T. Ison — Osgoode Hall Law School
J. Robertson — Canadian Airline Employees' Association — (appointed March 1982)
D. Sackett — McMaster University

Meetings Held	*Reports to Council*
April 26, 1982	August 17, 1982
July 21, 1982	November 30, 1982
August 25, 1982	
September 22, 1982	
October 26, 1982	
November 9, 1982	

TASK FORCE ON THE POSSIBLE HEALTH HAZARDS OF VISUAL DISPLAY UNITS (VDUs)

Terms of Reference:
To evaluate the available information on the possible hazards to human health associated with the use of visual display units.
The term health to include discomfort, degradation of visual acuity and excessive fatigue as well as better-defined disease states, such as cataracts.

Membership

Council Member
G.J. Stopps — Chairman

Others
R. DeMatteo — Ontario Public Service Employees' Union
S. Garnett — McMaster University
E. Kaegi — CIL
J. Keene-Moore — Bell Northern Research
J. Parker — University of Toronto
J. Purdham — Canadian Centre for Occupational Health and Safety
R. Roberts — McMaster University
S. Stuchly — University of Ottawa

Meetings Held	*Reports to Council*	*Resulting in*
April 20, 1982	August 17, 1982	Advisory
June 23, 1982	November 30, 1982	Memorandum 82-VI
August 4, 1982	January 12, 1983	Interim Report
September 10, 1982	February 8, 1983	February 25, 1983
October 13, 1982		
November 22, 1982		
December 17, 1982		
January 5, 1983		
March 9, 1983		

TASK FORCE ON THE IMPLEMENTATION OF THE OCCUPATIONAL HEALTH AND SAFETY ACT

Terms of Reference

i) To review the application and interpretation of the Act and regulations, with particular reference to such issues as:
  — the right to refuse work
  — the role of government
  — legal interpretations
  — responsibilities regarding health and safety information
ii) To examine the functioning of the joint health and safety committees, including the matter of access to information.
iii) To review the application and implementation of the designated substances regulations.
iv) To make appropriate recommendations.

Members

Council Members
A.D. Wolfson — Chairman (to July 21, 1982)
J.F. Mustard — Chairman (from July 22, 1982)
W.A. Barnes
R.T. Boldt (joined September 8, 1982)
J. Duffy
P.A. Fisher *
J. Gill **
E. Kaegi **
M.A. Taschereau
E.A. Waddell *

Others
K. Glassco — Energy and Chemical Workers Union (Polysar Ltd.)
J.N. Lockington * ** — DOFASCO
T. Meagher — OFL
R. Prichard — University of Toronto, Faculty of Law (Resigned February 22, 1983)
C. Schmidt — United Rubber Workers of America (Uniroyal Ltd.)
K. Swinton ** — University of Toronto, Faculty of Law

Meetings Held

Task Force	*Sub-Committee* Role of Government	*Sub-Committee* Legal Interpretations	*Reports to Council* Legal Interpretations
April 14, 1982	May 31, 1982	May 10, 1982	August 17, 1982
May 7, 1982	August 27, 1982	June 15, 1982	September 14, 1982
July 21, 1982	September 8, 1982	August 22, 1982	January 12, 1983
September 8, 1982	February 1, 1983	October 28, 1982	February 8, 1983
November 3, 1982			
January 5, 1983			*Resulting in*
March 30, 1983			Advisory Memorandum 82-VII

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* Member of Sub-committee — Role of Government
** Member of Sub-committee — Legal Interpretations

TASK FORCE ON THE INTERPRETATION OF HEALTH EFFECTS DATA AND THE ROLE OF ECONOMIC ANALYSIS IN THE STANDARD-SETTING PROCESS

Terms of Reference

- i) a) To examine the principles and procedures which should be employed to [i] evaluate health effects data and [ii] classify and rank health effects studies.
  - b) To examine [i] the appropriate role for economic analysis in the standard-setting process and [ii] the kinds of economic information (if any) which should be collected and analysed as part of the process for developing regulations.
  - c) To determine whether common principles can be applied to the interpretation and analysis of health effects and economic cost data.
- ii) To examine the manner in which health effects and economic information should be integrated in the regulation of hazardous substances.
- iii) To make recommendations to council in respect to these issues.

Members

Council Members
R.D. Fraser — Chairman
L. Heard
E. Mastromatteo (to 31 October, 1982)
C.J. Tuohy (appointed May, 1982)

Others
G. Atherley (alternate J. Purdham) — Canadian Centre for Occupational Health and Safety — (appointed September 1982)
E. Farber — University of Toronto
A.L. Gladstone — Ministry of Labour (ex-officio)
L. Jolly — Consultant
R. Roberts — McMaster University

Meetings Held	*Reports to Council*	*Resulting In*
April 27, 1982	August 17, 1982	Advisory Memorandum 82-V February 14, 1983
June 2, 1982	October 19, 1982	
July 27, 1982	November 30, 1982	
September 1, 1982		
October 4, 1982		

SPECIAL ADVISORY COMMITTEE ON CARCINOGENS

Terms of Reference

i) To examine the principles governing the regulation development process to determine how the process can effectively and efficiently identify, prioritize and regulate carcinogens.

ii) To propose recommendations on the policies and principles governing the development of regulations for carcinogens.

Members

J.F. Mustard — Chairman
M. Farber — Banting Institute
A.B. Miller — University of Toronto
D. McCalla — McMaster University
J.E. Till — Ontario Cancer Institute
R.T. Boldt (appointed February 8, 1983)
E.A. Waddell (appointed February 8, 1983)

Meetings Held	*Reports to Council*	*Resulting in*
March 11, 1983	April 13, 1982 May 11, 1982 June 8, 1982 September 14, 1982 October 19, 1982 November 30, 1982 January 11, 1983	Report of Special Advisory Committee, April 7, 1982 Discussion Paper "Control of Workplace Carcinogens"

An additional task force on **Potential New Hazards** — Phase Two, details of which appeared in last year's annual report, has been inactive during the past year. It is expected that the objectives of the study will be incorporated in the terms of reference of a new task force which wil be set up during the coming year to look at future developments in the area of occupational health and safety.

APPENDICES

APPENDIX A

Injuries, Permanent Disabilities and Fatalities Receiving First Payment of Compensation in 1981 by Year-End 1982, Classified by Nature of Injury

Name of Injury	*Major Permanent Disabilities*[1]		*Other Disabling Injuries*[2]		*Fatalities*[3]	
	No.	%*	*No.*	%	*No.*	%
Amputation or enucleation	6	2.02	874	0.54	0	0.00
Asphyxia, strangulation or drowning	0	0.00	0	0.00	9	4.37
Burn, scald-heat	1	0.34	4,180	2.57	4	1.94
Concussion, brain-cerebral	0	0.00	337	0.21	0	0.00
Contusion, crushing, bruise – intact skin	20	6.73	17,856	10.96	132	64.08
Cut, laceration, puncture – open wound	3	1.01	20,841	12.80	1	0.48
Dislocation	2	0.67	606	0.37	0	0.00
Electric shock, electrocution	0	0.00	245	0.15	11	5.34
Fracture	7	2.36	8,046	4.94	4	1.94
Hernia, rupture	0	0.00	1,810	1.11	0	0.00
Scratch, abrasion – superficial wound	1	0.34	5,648	3.47	0	0.00
Sprain, strain	131	44.11	45,347	27.84	1	0.48
Multiple injuries	6	2.02	1,079	0.66	7	3.40
Occupational injuries, unspecified	91	30.64	49,997	30.70	4	1.94
Occupational injuries, NEC[4]	0	0.00	48	0.03	1	0.48
Burn – Chemical	0	0.00	1,240	0.76	0	0.00
Tuberculosis only	0	0.00	4	0.00	0	0.00
Tuberculosis and pneumoconiosis	0	0.00	0	0.00	0	0.00
Contagious and infectious disease, NEC	0	0.00	151	0.09	1	0.48
Dermatitis	7	2.36	669	0.41	0	0.00
Freezing, frost-bite – environmental cold	0	0.00	82	0.05	0	0.00
Hearing loss or impairment[5]	0	0.00	955	0.59	0	0.00
Heat – sunstroke – environmental heat	0	0.00	23	0.01	0	0.00
Bursitis	0	0.00	35	0.02	0	0.00
Synovitis, tenosynovitis	1	0.34	531	0.33	0	0.00
Inflammation, irritation, NEC	2	0.67	294	0.18	0	0.00
Poisoning, systemic	1	0.34	657	0.40	1	0.48
Silicosis	2	0.67	30	0.02	0	0.00
Asbestosis	2	0.67	12	0.01	1	0.48
Pneumoconiosis, NEC	1	0.34	59	0.04	0	0.00
Radiation effects	0	0.00	1,034	0.63	0	0.00
Caisson's disease	0	0.00	5	0.00	0	0.00
Occupational illness, NEC	11	3.70	92	0.06	29	14.08
Non-personal damage	1	0.34	74	0.05	0	0.00
Other – preventive measures[6]	1	0.34	2	0.00	0	0.00
Total[7]	297	100.01	162,863	100.0	206	99.97

*Percentages are rounded to the nearest one-hundredth

1. This includes those who had received their first payment of compensation in 1981 and were receiving a pension as of December 31, 1982. 'Major' is arbitrarily defined as a permanent disability rating of 50% or greater. Lump sum payments are excluded.
2. Receiving first payment of compensation from the Workmen's Compensation Board in 1981.
3. Fatalities include those who had received their first payment of compensation in 1981 and were dead by year end 1982. These figures are different from those in the Workmen's Compensation Board's record of fatalities. The difference is explained by different definitions of fatality and by different time frames used.
4. NEC stands for 'Not Elsewhere Classified.'
5. The official WCB figure for hearing loss for 1981 is 968.
6. Under section 53 of the *Workmen's Compensation Act*, certain high risk individuals, whose health may be impaired by continued exposure to silica, asbestos or radiation may apply for and receive compensation while undergoing retraining. See the *Report of the Royal Commission on the Health and Safety of Workers in Mines* for further information.
7. Due to rounding, percentages do not add up to 100 per cent.

Source: Research Branch, Ministry of Labour, February, 1983.

APPENDIX B

Fatality Frequency Rates per Million Man-hours and Numbers of Fatalities for Major Industries in Ontario 1978, 1979, 1980 and 1981[1]

Industry	*1978 Number of Fatalities[2] attributed to:* Occupational Disease	*1978* Trauma	*1978* Fatalities per Million Man-Hours	*1979 Number of Fatalities attributed to:* Occupational Disease	*1979* Trauma	*1979* Fatalities per Million Man-Hours	*1980 Number of Fatalities attributed to:* Occupational Disease	*1980* Trauma	*1980* Fatalities per Million Man-Hours	*1981 Number of Fatalities attributed to:* Occupational Disease	*1981* Trauma	*1981* Fatalities per Million Man-Hours
Agriculture	1	6	0.10	1	4	0.07	1	5	0.08	0	11	0.15
Forestry	1	8	0.45	0	6	0.27	0	13	0.61	0	8	0.40
Mining, Quarrying and Oil Wells	12	11	0.32	9	7	0.24	28	24	0.74	8	11	0.26
Manufacturing	11	43	0.03	25	51	0.03	18	43	0.03	10	39	0.02
Construction	1	35	0.14	2	40	0.18	4	35	0.19	5	31	0.17
Transportation, Communication and Other Utilities	1	22	0.17	2	26	0.21	2	26	0.21	1	26	0.20
Trade	0	6	0.01	0	13	0.02	0	10	0.01	2	9	0.01
Community, Business and Personal Services	2	16	0.01	0	9	0.01	3	8	0.01	0	13	0.01
Public Administration	5	8	0.14	4	4	0.10	2	3	0.07	0	9	0.12
Other (Fishing)	0	0	0	0	1	0.90	0	0	0.00	0	0	0.00
All (Schedule 1 only)	34	155	0.04	43	161	0.03	58	167	0.05	26	157	0.03
All (Schedule 2 included)	36	187	—	52	183	—	64	187	—	32	174	—

1. 1981 Figures are provisional
2. Fatalities include those who received their first payment of compensation in 1978, 1979, 1980, and 1981 and were dead by year-end 1979, 1980, 1981 and 1982 respectively. These figures are different from those in the Workmen's Compensation Board's record of fatalities. The difference is explained by different definitions of fatality and by different time frames used.

Source: Research Branch,Ministry of Labour, February, 1983. The WCB rate number groups have been allocated to the industry categories by the Research Branch in compiling the data.

APPENDIX C

Compensated Work Injury Frequency Rate per Million Man-hours for Major Industries in Ontario, 1971–1981

Industry	*1971*	*1972*	*1973*	*1974*	*1975*	*1976*	*1977*	*1978*	*1979*[1]	*1980*	*1981*[2]
Agriculture	32.34	30.69	31.29	31.25	28.41	33.81	32.28	33.52	34.84	36.00	34.75
Forestry and Logging	83.05	98.38	107.19	98.75	79.35	70.30	79.05	85.91	79.46	82.39	75.89
Mining, Quarries and Oil Wells	40.60	41.64	49.92	58.93	63.66	68.32	63.65	53.24	47.12	62.12	50.05
Manufacturing	29.31	31.65	33.79	35.18	32.09	34.00	33.90	34.05	37.25	38.67	35.40
Construction	61.51	63.66	60.72	58.07	51.77	64.02	62.11	62.16	65.57	74.88	63.34
Transportation and Communication	55.37	55.70	58.37	55.56	50.93	55.27	55.71	57.16	64.05	65.27	59.64
Trade, Wholesale and Retail	17.93	18.82	18.82	18.73	16.92	18.05	18.09	18.35	18.96	19.15	17.58
Services											
Hospital	11.42	11.92	11.33	11.11	9.67	19.73	19.84	19.88	21.81	23.71	21.83
Teaching	8.03	8.42	8.75	9.41	8.56	9.16	9.23	8.82	9.78	10.43	10.24
All	10.84	11.65	10.96	10.47	9.36	10.29	10.57	10.61	11.53	12.61	11.41
Public Administration	31.31	34.66	31.13	28.61	27.71	30.43	31.70	31.11	32.32	33.82	30.60
Others (Fishing)	38.99	60.60	51.92	37.53	40.85	33.51	37.49	38.20	24.25	35.70	25.76
All Industries (Schedule 1)	26.76	28.10	28.72	28.95	25.73	29.02	28.40	28.07	29.89	31.17	28.04

1. 1979 data are slightly different from those shown in past year's annual report. Adjustments have been made in the figures shown for Manufacturing and All Industries.
2. 1981 data are provisional

Source: Research Branch, Ministry of Labour — February 1983, from Workmen's Compensation Board *'Final Accident Frequency and Cost Rate by Rate Number Report'* for each year. The WCB rate number groups have been allocated to the industry categories by the Research branch in compiling the data.

APPENDIX C-1

Number of Compensated Work Injuries for Major Industries in Ontario, 1971–1981[1]

Industry	*1971*	*1972*	*1973*	*1974*	*1975*	*1976*	*1977*	*1978*	*1979*	*1980*	*1981*
Agriculture	2049	1900	2154	2218	2059	2145	2178	2419	2481	2726	2599
Forestry and Logging	1651	1815	2118	2256	1540	1206	1449	1721	1784	1786	1502
Mining, Quarries and Oil Wells	4014	3682	4111	5084	5654	6234	5480	3877	3183	4451	3610
Manufacturing	51648	59580	68381	75043	66663	70809	68676	69161	79000	77272	70806
Construction	17750	18178	18306	19026	16959	18933	16791	15538	15162	15161	13443
Transportation and Communication	6114	6727	7328	7639	6880	7421	7511	7703	8525	8581	8074
Trade, Wholesale and Retail	9494	10715	11414	12593	11752	12932	12835	13243	14472	14652	13979
Services											
Hospital	4236	4560	4722	5096	5144	5150	5500	5592	6278	7005	7019
Teaching	445	542	588	624	585	904	1180	1121	1172	1103	1109
All	6410	7460	7841	8222	8072	9190	9687	10028	11414	12648	11973
Public Administration	1881	2319	2264	2232	2431	2615	2892	2829	2694	2504	2294
Others (Fishing)	32	53	49	34	35	28	31	36	27	37	32
All Industries (Schedule 1)[2]	105,724	117,531	129,276	140,067	127,774	137,567	134,210	133,268	146,192	147,926	136,440

1. 1981 data are provisional
2. The All Industries totals for 1974 and 1977 are slightly different from those shown in last year's annual report.

Source: Research Branch, Ministry of Labour — February, 1983, from Workmen's Compensation Board *'Final Accident Frequency and Cost Rate by Rate Number Report'* for each year. The WCB rate number groups have been allocated to the industry categories by the Research Branch in compiling the data.

APPENDIX D

Injuries Receiving Compensation in 1981 by Occupation Ranked in Descending Frequency per 100 employees Covered by the Workmen's Compensation Board of Ontario

Occupation[1]	*Disabling Injuries 1981*[2]	*Estimated Employment Covered by WCB (000)*[3]	*Estimated Injuries per 100 Employees Covered by WCB*
Managerial, professional	837	334	0.25
Natural Sciences	1,093	170	0.62
Social Sciences	713	59	1.21
Religion	14	8	0.18
Teaching	968	140	0.69
Medicine and health	5,515	165	3.34
Artistic and recreational	383	64	0.60
Clerical	9,243	731	1.26
Sales	4,314	399	1.08
Service	17,704	482	3.67
Agriculture	2,844	95	2.99
Fishing, hunting, trapping	31	1	3.10
Forestry and logging	1,462	10	14.62
Mining and quarrying	1,959	23	8.52
Processing	11,851	132	8.98
Machining	16,161	123	13.14
Product fabricating	24,645	425	5.80
Construction trades	15,673	212	7.39
Transport equipment operation	12,561	134	9.37
Materials handling	10,155	109	9.32
Other crafts and equipment	1,952	53	3.68
Not stated	9,271	—	—
Occupations, NEC[4]	14,017	—	—
	163,366	3,869	

1. Taken from *Canadian Classification and Directory of Occupations.* See Appendix D-1
2. Receiving first payment from the Workmen's Compensation Board of Ontario in 1981. Schedules 1 and 2.
3. Derived from Statistics Canada Labour Force Survey 1981. It is estimated that WCB covers approximately 92.5% of the employed labour force. Estimates for 'Service' exclude domestics, babysitters and barbers and those for 'Agriculture' combine the number of owner operators and the number of paid workers and employees.
4. NEC stands for 'Not Elsewhere Classified.'

Source: Research Branch, Ministry of Labour, report dated March, 1983.

APPENDIX D-1

Selected Occupations Defined by Subgroup from the Canadian Classification and Dictionary of Occupations

1. *Mining* and quarrying including oil and gas field operations have the following occupational groups included: foremen, rotary well-drilling, other rock and soil drilling, blasting, cutting, handling and loading, labouring and other elemental work, and not elswhere classified (NEC).

2. *Machining* and related occupations have these groups included: foremen *metal machining*: tool and die making, machinist and machine tool setup, machine tool operating; *metal shaping and forming*: forging, sheet metal workers; welding and flame cutting, boilermakers, platers and structural metal workers; foremen *wood machining*: wood pattern making, wood sawing and related work, wood sanding; foremen *clay, glass and stone and related materials*: cutting and shaping, abrading and polishing; foremen *other machining* and related work, engravers and etchers, filing, grinding, buffing, cleaning and polishing work, inspecting, testing, grading and sampling occupations.

3. *Forestry* includes these groups of occupations: foremen forestry and logging, forestry conservation, timber cutting, log hoisting, sorting, moving, labouring, forestry and logging NEC, log inspecting, grading and scaling.

4. *Materials handling* has these occupations grouped together: foremen materials handling NEC, hoisting operations NEC, longshoremen, stevedores and freight handlers, materials handling equipment operators NEC, packaging, labouring in materials handling work.

5. *Processing* occupations are composed of: *mineral ore*: treating, crushing and grinding, mixing, filtering, melting and roasting; *metal processing*: smelting, converting and refining, metal heat treating, metal rolling, moulding, coremaking and metal casting, metal extruding and drawing, plating and metal spraying: *clay, glass and stone* furnacemen and kilnmen, separating, grinding, crushing and mixing, forming; *chemicals, petroleum, rubber, plastic and related materials:* mixing and blending, filtering, straining and separating, distilling, subliming and carbonizing, coating and calendarizing; *food, beverage and related*: flour and grain milling, baking, confectionery making, slaughtering and meat cutting, canning, curing and packing, fish canning, curing and packing, fruit and vegetable canning, preserving and packing, milk processing, sugar processing, beverage processing; *Wood*: sawmill sawyers, plywood making, wood treating; *Pulp and paper making*: cellulose preparing, papermaking and finishing; *Textiles*: fibre preparing, spinning, winding, weaving, knitting, bleaching, finishing; *Other*: tobacco, hide and pelt. Foremen, inspecting, testing and grading, elemental labour in all above groups.

6. *Transportation and Equipment* operating occupations have the following sub-groups: air transport, railway transport, water transport, motor transport and the specific occupations in each.

7. *Construction* has these sub-groups: excavating, grading and paving, electrical power, lighting and wire communications equipment erecting, installing and repairing and construction trades—carpenters, brick and stone masons, concrete finishing, plasterers, painters and paper hangers, insulating, roofing, pipe-fitting, structural metal erectors, glazers. Foremen inspecting, testing, grading and sampling, and elemental labour are included in the above where appropriate.

8. *Product fabricating* classification is composed of: metal products; electrical, electronic and related equipment; wood products; textile, fur and leather products; rubber, plastic and related products; mechanics and repairmen except electrical; and other: jewellery and silverware, marine craft, paper products, and painting and decorating.

Ontario
Ministry of
Labour

Advisory Council
on Occupational Health
and Occupational Safety

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Volume

2

Ontario

Advisory Council on Occupational Health and Occupational Safety

Fifth Annual Report
April 1, 1982
to March 31, 1983

Volume 2

Mandate and Objectives

The function of the Advisory Council is and it has power to*:

a) make recommendations to the Minister of Labour relating to programs of the ministry in occupational health and occupational safety; and
b) advise the minister on matters relating to occupational health and occupational safety which may be brought to its attention or be referred to it.

To achieve this Council has set the following objectives:

Primary Objective
To advise the Minister of Labour on all matters relative to occupational health and safety in Ontario.

Secondary Objectives

1. To ensure as far as possible that the policies and programs in occupational health and safety effectively minimize the risks to health and safety in all workplaces in Ontario.
2. To ensure as far as possible that knowledge about occupational health and safety is available to management, labour and the public and that it is understood by them.
3. To assist in promoting and establishing mechanisms involving management and labour to solve problems in occupational health and safety.
4. To ensure as far as possible that there is appropriate manpower training and development for the occupational health and safety field.
5. To review periodically the effectiveness of the policies and programs implemented to achieve objectives 1 to 4. **

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*The Occupational Health and Safety Act.s 10(7).
**added June, 1980.

Advisory Council on Occupational Health and Occupational Safety

Fifth Annual Report
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Volume 2

400 University Ave.,
15th Floor,
Toronto, Ontario
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Copies of this report are available from:

Ontario Government Bookstore
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Toronto, Ontario M7A 1N8

ISSN 0708-5117

Table of Contents

Discussion Paper on the Control of Workplace Carcinogens v

Briefs Submitted in Response to the Discussion Paper 35

Algoma Steel Corporation Limited 36
BASF Canada Inc. 43
Bayer (Canada) Inc. 49
CIL Inc. 87
Canadian Centre for Occupational Health and Safety — Brief 1 91
Canadian Centre for Occupational Health and Safety — Brief 2 93
Canadian Chemical Producers' Association 97
Canadian Manufacturers' Association 109
City of Toronto Department of Public Health 113
Concord Scientific Corporation 118
Council of Safety Associations 122
Dow Chemical Canada Inc. 129
Dupont Canada Inc. 239
Energy and Chemical Workers Union 262
Environment Canada 268
Falconbridge Limited 271
Gulf Canada Limited 292
Imperial Oil Limited 295
INCO Limited 297
Mines Accident Prevention Association of Ontario 307
Office of Occupational Health and Safety — University of Toronto 310
Ontario Federation of Labour 312
Ontario Hospital Association 334
Ontario Hydro 341
Ontario Medical Association 351
Ontario Mining Association 352
Ontario Petroleum Association and the Petroleum Association for Conservation of the Canadian Environment 389
Ottawa-Carleton Regional District Health Council 399
Provincial Building and Construction Trades Council of Ontario 404
Public Service Alliance of Canada 410
Shell Canada Limited 414
Stelco Inc. 422
United Rubber, Cork, Linoleum & Plastic Workers of America International Union 426

THE CONTROL OF WORKPLACE CARCINOGENS

A DISCUSSION PAPER PREPARED BY: THE ADVISORY COUNCIL
ON OCCUPATIONAL HEALTH AND OCCUPATIONAL SAFETY

June 30, 1982

TABLE OF CONTENTS

Chapter		Page No.
I	Introduction	1
II	An Approach to the Problem of the Identification and Classification of Chemical Substances in the Workplace and the Control of Carcinogens and Suspect Carcinogens.	9
	1. New Chemicals	9
	A Identification and Classification	12
	B Regulatory Control Measures	16
	2. Chemicals Not Considered New	18
III	Issues for Consideration	20
	Chart - Classification of Substances in the Workplace	31
	Footnotes	32

I. INTRODUCTION

The health of an individual, as has been pointed out in 'A New Perspective on the Health of Canadians',[1] is the product of his or her genetic characteristics interacting with the environment and the individual's lifestyle. Obviously, an important part of one's life has to do with one's place of employment, work activities and the materials to which one is exposed in the workplace. The health of workers is a major concern of workers themselves, of employers and of the Ministry of Labour, and the issue of carcinogens in the workplace is one of increasing prominence.

All deaths in the workplace are of concern to society. They are equally serious whether the worker dies of occupationally-induced cancer or as a result of a traumatic accident. Why, then, have carcinogenic substances been chosen for special consideration? The reasons are complex. Although there are many fatal diseases, the fear of contracting cancer probably outweighs other fears of this kind. Cancer has a number of unique characteristics that suggest both a reason for the emphasis it receives and a justification for developing a distinct regulatory scheme for carcinogens. As Doll and Peto[2] have recently emphasized, most internal cancers are incurable. There is a high level of uncertainty with regard to the mechanisms involved and the dose-response relationship. The long latent period between the initial exposure and the ultimate appearance of the disease serves to intensify our fears and our feeling of powerlessness.

Perhaps one of the most cogent arguments that can be made in favour of regulating potential new carcinogens lies in the fact that cancer can be prevented by controlling exposure to carcinogens and that such control is feasible. In the case of new chemicals, potential carcinogenicity can be established and appropriate regulations and controls decided upon before the substances become an inextricable part of an operating system or process. Thus, from a practical point of view, there is some justification in singling out new carcinogens for special regulatory treatment. Our enhanced understanding of the causes of cancer and the heightened public awareness in recent years of the need to control the disease, if at all possible, through a program of prevention rather than cure, all tend to reinforce the argument for immediate and specific action in this area. It could well be, of course, that a regulatory model established now for carcinogens should eventually be adapted and applied to the control of other toxic substances which, while non-carcinogenic, have other adverse health effects.

The bulk of the evidence in respect to workplace carcinogens has been obtained by examining the effects on workers' health of past exposures. Since techniques now exist for assessing the potential carcinogenicity of a chemical, it is no longer necessary to rely solely upon evidence produced after exposure at a stage when it is too late to protect the health of an affected worker. (It is important to keep in mind that very few cancers can be cured by medical treatment once an individual is affected.) This discussion paper addresses the question of how our new knowledge could be applied in the future in order to minimize the risk of individuals developing cancer because of exposure to workplace carcinogens.

The International Labour Organization, in its Occupational Cancer Convention, 1974,[3] made the following statement:

> ### Article 2
>
> 1. Each member which ratifies this Convention shall make every effort to have carcinogenic substances and agents to which workers may be exposed in the course of their work replaced by non-carcinogenic substances or agents or by less harmful substances or agents; in the choice of substitute substances or agents account shall be taken of their carcinogenic, toxic and other properties.
>
> 2. The number of workers exposed to carcinogenic substances or agents and the duration and degree of such exposure shall be reduced to the minimum compatible with safety.

The need for a rational and integrated system for identifying, assessing and controlling cancer-risks (both those associated with current practices and the potential hazards of new chemicals) is widely accepted. There are, however, divergent views on the best policy to adopt.

Ideally, no human should be exposed to carcinogenic materials at any level. However, given the occurrence of carcinogens in the environment, this ideal is unattainable. Further, the sensitivity of our analytical methods is such that we can often detect chemicals at levels that may be well below those that have detectable biological effects. The difficulties involved in establishing appropriate controls and the principles to be applied may vary according to whether a carcinogen is new or already in use in the workplace. A number of factors will dictate the difference in approach. The economic problems involved in instituting a system of controls for carcinogenic substances which are already in use are obviously much greater than would be the case for new carcinogens. Also, to a large extent, the differences in the approaches to 'old' and to new carcinogens reflect the distinction between substances or agents about which we have information and those about which we have little or no evidence of carcinogenicity. More information is available on a number of existing carcinogenic substances for the simple reason that epidemiological data have been gathered on populations that have been inadvertently exposed to them. Such data are not available on new substances.

One carcinogenic agent that has been under scrutiny for almost a century is ionizing radiation. From the beginning, the human race has been exposed to several natural sources of 'background' radiation, including terrestrial and cosmic radiation and radiation from radioactive elements in our bodies.

Occupational exposure to ionizing radiation only became significant late in the nineteenth century with the discovery of x-rays and radioactivity. The harmful effects of ionizing radiation were very quickly identified.

The nuclear power industry, which is only a small contributor to the total radiation load, is an example of an industry that has been able, over the years, to formulate a consistent approach to worker exposure to a well-known carcinogenic hazard by balancing a number of economic, social and ethical considerations.

Radiation hazards have been studied for many years and fairly reliable estimates of the attendant risks are available. In the nuclear power industry a philosophy has been developed, as expressed by the International Commission on Radiological Protection (ICRP),[4] aimed at providing a satisfactory level of safety to an exposed group. Basically, there are three principles embodied in this approach: 1) exposure to a toxic agent must be justified by the benefits to society that its use confers, 2) the principle of ALARA which states that we must bring exposures down 'As Low As Reasonably Achievable,' which may mean that they are below the maximum permissible limits. In so doing, judgements about economic and social factors have to be made, and 3) the ICRP endorses the notion of acceptable risk. It proposes maximum permissible exposure limits to be set so that, on average, the risk to a worker is in the range of that experienced in recognized safe industries, such as service industries.

The above approach, although generally accepted within the nuclear power industry itself, is not endorsed by all sectors of society as being an acceptable approach to the hazards involved in the generation of electricity. The argument has been made by some that the approach to radiation hazards is even less appropriate when transferred to new chemicals because of the great disparity in the amount of information available in the two areas. Whereas there is quantifiable evidence on the effects of radiation, there is little or no information on many of the new chemicals being introduced into the workplace. It is not possible, so the argument goes, on the basis of present evidence, to assess the degree of risk in man from exposure to chemicals found to be mutagenic in short-term tests and carcinogenic in animal tests. Chemicals will have to be introduced and exposures monitored for 20 to 30 years before an estimate of risk can be made. At that time, it may be possible to determine an 'acceptable' level of exposure. It is argued that no benefit to society can be worth subjecting a work force to a risk that we are unable to quantify at this stage.

Those who take the position that no increased risk is acceptable opt for a zero exposure standard. They argue that in the absence of data on dose-response and assuming a linear dose-response relationship, there must be zero exposure to workplace carcinogens in order to ensure zero risk from occupational exposure.

The application of the ICRP philosophy to chemicals that are currently in use is thought by some to be appropriate in certain cases. It can be argued that there are some known carcinogenic chemicals in use on which there are epidemiologic data of sufficient precision that levels of exposure can be set that comply with the ICRP principles.

The lesson that emerges from such a debate is that in establishing controls for new substances, estimates of risk will generally have to be made without the assistance of epidemiologic data. There is, therefore, an urgent need to ensure that there is a record of health effects where workers have been inadvertently exposed to carcinogens. The Special Advisory Committee on Carcinogens discusses in its report[5] the need for epidemiologic surveillance of persons exposed to hazardous substances, and the various approaches that can be adopted in gathering epidemiologic evidence.[6]

Part of the controversy surrounding regulation of carcinogens is due to misconceptions of the nature of cancer and its causes. It was for this reason that council sought scientific advice from a special advisory committee of experts in the field. This committee was also asked to advise on the various methods of pre-screening for carcinogens.

It should be made clear that, in the discussions that follow, the term 'substance' refers to chemical substances. Although the subject of radiation-induced cancers is dealt with in the report of the Special Advisory Committee,[5] council has not attempted to discuss a possible regulatory approach in this area. It should also be noted that the subject of the potential carcinogenicity of substances produced as by-products of industrial processes has not been addressed in this paper. It was felt that, although the control principles and the basic philosophy behind the regulatory approach for new chemicals would apply equally to chemical by-products, the testing principles involved could be sufficiently different to warrant treatment in a separate discussion paper.

Although the primary focus of this paper is on potential new carcinogens, consideration is also given to the treatment of existing carcinogens.

Council's mandate is to advise the minister on the adoption of a regulatory scheme for this province. It is noted that in other jurisdictions, carcinogen control programs have been organized on a national scale. While this is obviously a desirable goal for this country also, the political realities in Canada may make it difficult to achieve, at least for the foreseeable future. It must, however, be recognized that any independent action on the part of the Government of Ontario in controlling carcinogens and suspect carcinogens would be of limited effect and could have potentially serious and disruptive economic implications if proposals for regulation were not co-ordinated with existing and anticipated regulatory schemes at the federal and other provincial levels. It is important, therefore, that representations be made to the federal government calling for assistance in the financing of individual provincial initiatives and for the establishment and co-ordination of a nationwide program. As an essential part of such a program, the highest priority should be given to the objective of assembling and co-ordinating the available data. The task of establishing a nationwide program could be co-ordinated through agencies such as the federal Department of

Labour, the Department of National Health and Welfare and the Canadian Centre for Occupational Health and Safety.

The issues for consideration, and some possible approaches to these issues, contained in Chapter 3 of this paper, have arisen out of the deliberations of council and the advisory committee to date. Council is not at this time committed to any particular point of view and will welcome alternative suggestions which will be considered before preparing its advisory memorandum to the minister.

II. AN APPROACH TO THE PROBLEM OF THE IDENTIFICATION AND CLASSIFICATION OF CHEMICAL SUBSTANCES IN THE WORKPLACE AND THE CONTROL OF CARCINOGENS AND SUSPECT CARCINOGENS

The following approach is one that might be adopted by the ministry in the identification, classification and control of carcinogens and potential carcinogens. Other approaches are, of course, possible. The purpose of this outline is to identify issues and generate discussion.

1. New Chemicals

In developing this scheme, council has considered the approach adopted in other jurisdictions, including the European Economic

Community[7] and the policy under consideration in the United States.[8] There appears to be a general acceptance of the philosophy that all new chemicals should be screened and that if any are found to be carcinogens or potential carcinogens, their application in industry should be regulated.

Regulations for the control of carcinogens and suspect carcinogens, to be used in the workplace in Ontario, could be established by the minister after appropriate public discussion. In reaching his final decision, the minister might wish to consult solely with ministry staff. Alternatively, he might supplement the advice provided by his ministry with opinions offered by an advisory committee or committees[9] struck by the minister for the purpose of advising on this and other aspects of the regulatory program. Any such committee(s) should be established by the minister after full consultation with all the groups involved in the area. Its membership should be broadly representative of the various groups and its advice should be made public. The committee might be advisory to the minister himself or to the ministry.

The responsibilities of the advisory committee might include the following:

1) to advise the minister on testing procedures and to approve guidelines for interpreting the results of short-term and animal tests.

2) to offer advice to the minister, in the circumstances described below, on the need for testing or further testing of certain chemical substances.

3) to recommend to the minister, in the circumstances described below, the appropriate categories for chemical substances.

4) to make recommendations to the minister with regard to the suitability of substitutes for known carcinogens.

5) to advise the minister on the appropriate regulatory controls for carcinogens and suspect carcinogens.

In deciding upon the appropriate regulatory controls for workplace carcinogens and suspect carcinogens, account should be taken of the risk that each of these agents poses to humans. This assessment should be based, in part, on the tumour-inducing potency of the compound in animals. Present knowledge, however, does not enable this to be done with any precision and the decisions would have to take note of this uncertainty. In addition, economic and social considerations would have to be weighed in arriving at the appropriate regulatory controls.

A **Identification and Classification** (See chart page 31 which summarizes this approach.)

Three categories might be employed:

Category I - Substances confirmed as carcinogens.

Category II - Substances about which there is some uncertainty as to their carcinogenicity.

Category III - Substances which are considered to be non-carcinogenic.

The following steps could be taken in order to ensure that new chemical substances were placed in the appropriate category.

Reporting requirements could be established calling for full disclosure of the possible carcinogenicity of any new[10] substance to be manufactured or imported. Unless these requirements were met by the manufacturer or importer, who would be responsible for providing test results,[11] the substance could not be manufactured or imported. (Slightly less stringent requirements could apply in the case of substances to be marketed in quantities of less that one tonne[12] per annum, as discussed below.) Reliable information developed in any external jurisdiction concerning the possible carcinogenicity of a substance would be acceptable.

It is generally considered impractical to attempt to regulate substances that are to be used in very small quantities. A one tonne rule[13] could be applied to all new chemicals that were not considered suspect as a result of the initial assessment. (See below.) Where such chemicals were to be marketed in quantities of less than one tonne per annum, they should be subject to limited reporting requirements only, except where the competent authority determined that there was a possibility of high risk due to the manner in which the chemicals were to be used. Outline reporting requirements similar to those contained in the United Kingdom Interim Guide to Notification of New Substances could be considered.[14]

In developing the information needed to meet the reporting requirements, all new chemicals should be assessed for their chemical structure and relationship to known carcinogens. (Substances should be assessed as used because of the likely presence of impurities.) Where, after the initial assessment, it was determined that the chemical structure of the substance was similar to that of a known carcinogen, where it was known to be subject to tissue accumulation or where earlier studies suggested that long-term exposure might lead to the development of cancer, the substance should go directly into long-term animal testing, regardless of the quantities to be used. Where the results of these tests were positive, the substance should be placed in Category I. Where they proved non-positive, the results could be referred to the advisory committee, which would advise the minister on whether the substance should be placed in Category II or III.

The placing of a substance in Category III would mean that no surveillance (for carcinogenicity) would be required, of workers exposed to the substance and there would be no mechanism provided for detecting errors of judgement on the part of the committee. It would, therefore, have to be made clear that if members of the committee had any doubts whatsoever about the safety of a substance, the appropriate recommendation would be to place it in Category II. The criteria applied by the committee in recommending appropriate categories and regulatory controls should be subject to periodic review by the ministry.

Where the initial assessment did not indicate an immediate need for animal tests (and the developers themselves did not decide to have the substances subjected to animal testing at that stage), all new chemicals to be marketed in quantities of one tonne per annum or more should be subjected to short-term tests.

If the results of the short-term tests were positive or conflicting, the substance should automatically undergo long-term animal tests. Positive results from the long-term tests would place the substance in Category I. Non-positive results could be referred to the advisory committee for ultimate classification in Category II or III, as discussed above.

If the results of the short-term tests were non-positive, the manufacturer or user should have the option of either putting the substance into long-term animal tests or having it referred to the advisory committee. Should the manufacturer choose to go directly to animal tests, the substance would be classified as follows: Following a positive result, the substance would be placed in Category I. Following a non-positive result, it would be placed in Category III.

If the matter were referred to the advisory committee, the substance might ultimately be placed in Category I, II or III. After duly considering this evidence and other relevant factors, the committee might feel that the results of the short-term tests were sufficiently clear to permit it to recommend that the substance be placed in Category II or III. However, if the committee felt that further information was needed, it might recommend that long-term animal tests be required, after which the substance would be placed in Category I if the tests proved positive and in Category III if they proved non-positive.

Where a compound was generally regarded as a non-carcinogen or where it was a 'variant' of a safe compound it would be placed in Category III.

The ministry should make an index of new substances available to the public, showing the category in which each substance had been placed. The data base that had led to the categorization should be made available for public scrutiny. A review of the provisions of section 34(1)(b) of The Occupational Health and Safety Act might be required in order to determine whether it would be in the public interest to maintain confidentiality in the case of substances categorized as carcinogens or suspect carcinogens.

B Regulatory Control Measures

A number of possible measures for the control of Category I and II substances are set out in the Issues for Consideration, beginning on page 24. Basically, the approach might be as follows:-

Category I - Where there is certainty that a substance is a carcinogen, its use would be regulated.

Category II - Substances about which there is some uncertainty as to their carcinogenicity would be controlled as suspect carcinogens.

Category III - Substances that are considered to be non-carcinogenic could be used without surveillance or restrictions unless such measures were required for other purposes.

The establishment of testing requirements and regulatory controls must be accompanied by an effective means of enforcement. One method of ensuring compliance is through a permit or licensing system, whereby no carcinogen or suspect carcinogen can be used unless duly authorized by the competent authority.[15] The licensing system for radioactive isotopes might serve as a model.

The actual day-to-day monitoring of the use of new substances can only occur in the workplace itself. Employers should be required to disclose information about new chemicals and possible hazards to the joint health and safety committees, or, where no committees are established, to the work force. All containers in use should be meaningfully labelled with highly visible colour coded indications of carcinogenic hazard.

If a now substance were introduced without appropriate disclosure, members of the joint health and safety committee or the work force should ask management to make the information available. If management failed to do so, members of the committee or the work force should have the right to ask the government to take appropriate action, which might entail the imposing of a suitable financial penalty. Some have even considered the idea that offending parties should lose their protection from civil liability under the Workmen's Compensation Act if problems subsequently arose.

Where a company introduced a known or suspect carcinogen into the workplace and failed to meet acceptable standards, the company could be liable to a penalty in excess of those currently available under section 37(1) of The Occupational Health and Safety Act.

2. Chemicals Not Considered New

Substances that were not new - i.e. those on the Environmental Protection Agency (EPA) list or those currently in use in Ontario - should, where appropriate, be subject to the above testing procedures unless sufficient data were already available for them to be accurately categorized. The ministry, in consultation with the advisory committee, should determine which of the substances on the EPA list or currently in use in Ontario have not been adequately assessed for their potential carcinogenicity. Priorities should be set for the testing of such substances. The cost of such testing should be borne by the manufacturer of a substance currently in use in Ontario.

The ministry should make a systematic attempt to have the substances on the EPA list and those currently in use in Ontario properly categorized within a period of five years. It would probably be advisable for the ministry to do this in collaboration with other jurisdictions or organizations, such as the International Labour Organization.

Where a chemical that was not considered new was to be used in a newly-constructed plant*, it should be automatically subject to the same testing and classification procedures as those employed for new chemicals.

Where it was determined, on the basis of reliable evidence produced in this or any other jurisdiction, that a substance that was not considered new should be placed in Category I, where it was sufficiently beneficial to justify its continued use and where no suitable replacement was available, it should be subjected immediately to regulatory controls. Where the substance was to be used in a new plant these controls would be the same as those employed for new substances. Similarly, for substances placed in Category II, regulatory requirements should vary depending upon whether the substance was to be used in an existing plant or whether a new plant was to be built. In the latter case, appropriate regulatory controls should be instituted immediately. Where these substances were to be used in existing plants, somewhat less stringent regulatory controls would apply for an initial period. After five years, all users of Category I or II substances, whether in existing or new plants, should be required to meet the standards adopted for new substances.

Provision should be made for the relaxation of the above regulatory requirements in order to permit research and other activities where appropriate exemptions are warranted.

* either built from the ground up or converted for different purposes.

III. ISSUES FOR CONSIDERATION

Council now sets forth some of the issues that have been raised in the course of its recent deliberations. While recognizing that this list of issues may be incomplete, council believes that the answers to these questions will be of fundamental importance in establishing an effective policy for the control of workplace carcinogens.

Issue No. 1 - National and International Co-ordination and Co-operation in the Control of Carcinogens

1) Should representation be made, through the appropriate channels, to the federal government calling for assistance in the financing of individual provincial initiatives and for the establishment and co-ordination of a nationwide carcinogen program, through agencies such as the federal Department of Labour, the Department of National Health and Welfare and the Canadian Centre for Occupational Health and Safety?

2) As part of a national program, should the federal government or national agency be encouraged to give the highest priority to the objective of assembling and co-ordinating the available data from this and other jurisdictions, with regard to the carcinogenicity and potential carcinogenicity of chemical substances?

3) In establishing priorities for the testing of chemicals and in deciding upon appropriate regulatory controls for carcinogens and suspect carcinogens, should the Ontario Ministry of Labour work in close collaboration with international organizations such as the International Labour Organization? Should due regard be paid to international agreements such as the ILO 'Convention concerning prevention and control of Occupational Hazards caused by Carcinogenic Substances and Agents'?

Issue No. 2 - Advisory Committee(s)

Should an advisory committee(s) be established with the responsibility for advising the minister (or the ministry) on all aspects of the regulatory program for carcinogens? In particular, should the advisory committee make recommendations with regard to the appropriate categories and regulatory controls for chemical substances? Should the criteria applied by the committee be subject to periodic review by the ministry?

Issue No. 3 - Reporting Requirements for New Chemicals

1) Should the minister establish reporting requirements for full disclosure of the possible carcinogenicity of any new chemical

to be introduced into the workplace in Ontario?

2) Should limited reporting requirements apply to new chemicals to be marketed in quantities of less than one tonne per annum unless, after an initial assessment, (see Issue No. 4) they were considered suspect?

Issue No. 4 - Testing Requirements for New Chemicals

1) Should the minister establish regulations calling for the examination of all new chemicals on the basis of their chemical structure and relationship to known carcinogens?

2) Following such initial assessment, should all new chemicals (with the exception noted in No. 3 above) be subject to testing requirements as outlined on pages 12-16 above?

Issue No. 5 - Testing Procedures

(For further details, see 'Summary of Testing Requirements' in the Report of the Special Advisory Committee on Carcinogens, on pages 170-1 of the Fourth Annual Report of the Advisory Council on Occupational Health & Occupational Safety, 1981-82).

1) Should a standard testing program be developed by the ministry in consultation with the advisory committee?

2) If such a program were to be developed, should it incorporate any or all of the following requirements:

   a) Where long-term animal tests were required, should the procedure outlined in the National Cancer Institute (USA) 'Guidelines for Carcinogen Bioassay in Small Rodents', 1976, be followed?

   b) Where required, should a minimum of two appropriate short-term tests be conducted on a substance?

   c) Should such tests be carried out on commercial samples of chemicals rather than on purified preparations (or in addition to)?

   d) Should the formal testing requirements, both for long-term animal tests and for short-term in vitro tests, established by the ministry, be reviewed every three years?

Issue No. 6 - The Classification of New Chemicals

Should all new substances be placed in Categories I (carcinogens), II (suspect carcinogens) or III (non-carcinogenic) according to the criteria set out on pages 12-16 above?

Issue No. 7 - The Control of New Chemicals

If the classification scheme referred to in Issue No. 6 is thought to be appropriate, should the following measures be adopted:

1) Where a substance is placed in Category I, should its use be regulated?

2) Where a suitable substitute for a Category I substance is available for one or more uses, should occupational exposure to the Category I substance be permitted for those uses?

3) Where it is determined that a Category I substance is needed and that no suitable substitute is available, should its use be permitted, with the requirement that there be no detectable exposure of the work force, or should permissible exposure limits be set?

4) Should Category II substances be treated as suspect carcinogens?

5) Should permissible exposure limits be set for Category II substances?

6) Should the appropriate standards for Categories I and II substances be met through the use of engineering and work-practice controls?

7) Should the use of personal protective equipment be reserved for maintenance purposes and for emergency use only?

8) Should suitable epidemiological surveillance of workers exposed to Categories I and II substances be maintained?

9) Should the use of Category III substances be permitted without surveillance or restrictions unless such measures were required for other purposes?

Issue No. 8 - The Testing and Classification of Chemicals Not Considered New

1) Should the ministry, in consultation with the advisory committee, determine which of the substances on the EPA list or currently in use in Ontario have not been adequately assessed for their potential carcinogenicity?

2) Should priorities be set for the testing of such substances?

3) Where it is considered necessary to test a substance currently in use in Ontario, should the cost of such testing be borne by the manufacturer?

4) Where a chemical that is not considered new is to be used in a newly-constructed workplace, should it be automatically subjected to the same testing and classification procedures as are employed for new chemicals?

5) Should the ministry make a systematic attempt to have the substances on the EPA list and those currently in use in Ontario properly categorized according to the classification system outlined above within a period of five years, making full use of information developed in other jurisdictions?

Issue No. 9 - The Control of Chemicals Not Considered New

1) Where a chemical, not considered new, is placed in Category I, and is sufficiently beneficial to justify its

continued use and where no suitable replacement is available,

  a) When used in a new plant, should it be subjected immediately to the same regulatory controls as are employed for new substances?

  b) When used in an existing plant, should it be subjected immediately to appropriate regulatory controls?

2) Where a chemical, not considered new, is placed in Category II,

  a) When used in a new plant, should it be subjected immediately to appropriate regulatory controls?

  b) When used in an existing plant, should it be subjected to somewhat less stringent regulatory controls for an initial period?

3) After an initial period of five years, should all users of chemicals that are not considered new be required to meet the standards set for new chemicals, regardless of whether the substances are to be used in new or existing plants?

Issue No. 10 - Epidemiologic Surveillance

1) Should the minister ensure that appropriate epidemiologic surveillance is provided where individuals are known to have been exposed to established or suspect carcinogens?

2) Should employers be required to establish group and individual exposure records suitable for epidemiologic surveillance?

3) Should the minister seek to ensure that appropriate resources are made available to the Ontario Cancer Treatment and Research Foundation in order to guarantee continuance of the Ontario Cancer Registry?

Issue No. 11 - The Provision of Information to the Work Force and to the Public

1) Should the ministry ensure that members of joint health and safety committees or, where no committees are established, members of the work force are provided with information, not only on potential hazards, but also on the chemical structure of any new substance, regardless of whether it is considered by the employer to be safe?

2) Should the ministry establish a procedure to ensure that details of the chemical structure of, and the health effects produced by, a new substance are available to the joint health and safety committee (or the work force) in the event that management fails to provide this information?

3) Should the minister urge the governments of Canada to work with industry, workers and the Canadian Centre for Occupational Health and Safety to develop a labelling and colour-coding system that would alert users and members of the work force to the presence of a carcinogen or suspect carcinogen in any substance to be used?

4) Should the minister make an index of new substances available to the public, showing the category in which each substance has been placed? Should the data base that has led to this categorization also be made available for public scrutiny?

5) Should the confidentiality provisions of section 34(1)(b) of the Act apply in the case of carcinogens, or should there be full disclosure of all available information to the work force and to the public?

Issue No. 12 - Penalties for Non-Compliance with The Regulation

Should an employer who introduces a known or suspect carcinogen into the workplace and fails to meet acceptable standards be liable to a penalty in excess of those currently available under section 37(1) of *The Occupational Health and Safety Act*?

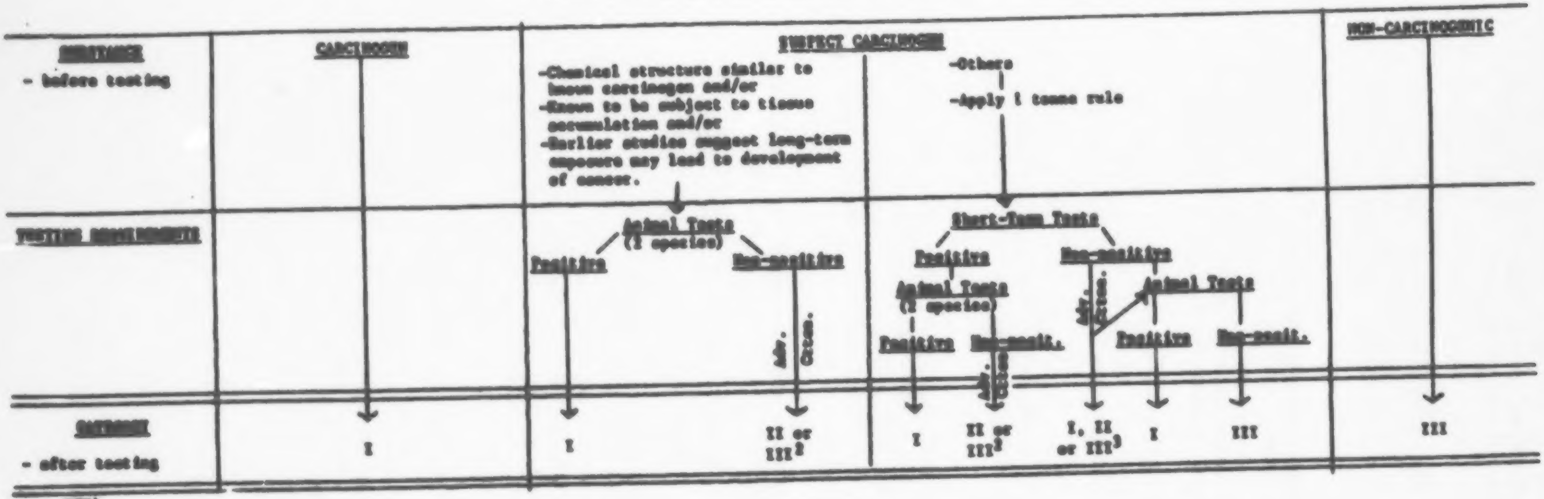
Issue No. 13 - Research

Should provision be made for the relaxation of the regulatory requirements in order to permit research in the following areas:

a) Research targetted toward the development of new chemicals?

b) Medical research involving the use of carcinogens for scientific or therapeutic purposes?

CLASSIFICATION OF SUBSTANCES IN THE WORKPLACE [1]


SUBSTANCE
- before testing
TESTING REQUIREMENTS
CATEGORY
- after testing
CARCINOGEN
I
SUSPECT CARCINOGEN
-Chemical structure similar to known carcinogen and/or
-Known to be subject to tissue accumulation and/or
-Earlier studies suggest long-term exposure may lead to development of cancer.
Animal Tests (2 species)
Positive
Non-positive
Adv. Cttee.
I
II or III[2]
-Others
-Apply 1 tonne rule
Short-Term Tests
Positive
Animal Tests (2 species)
Positive
Non-posit.
Adv. Cttee.
Non-positive
Adv. Cttee.
Animal Tests
Positive
Non-posit.
I
II or III[2]
I, II or III[3]
I
III
NON-CARCINOGENIC
III

KEY

CATEGORY I - CARCINOGEN
CATEGORY II - SUSPECT CARCINOGEN
CATEGORY III - NON-CARCINOGENIC

Footnotes:

1. For detailed discussion, see pages 12-16.

2. Depending upon recommendation of advisory committee and decision of minister.

3. As in 1 above, advisory committee recommends either Category II or III. Committee might, where appropriate, recommend that animal tests be required. Positive results of these tests would place the substance in Category I; non-positive results would place it in Category III.

Footnotes

1. Lalonde, M. A New Perspective on the Health of Canadians. A Working Document. Department of National Health and Welfare, (Ottawa 1974).

2. Doll, R. and Peto, R. The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the United States Today. Journal of the National Cancer Institute, vol. 66, no. 6, 1981, pp.1191-1308.

3. International Labour Organization. Convention No. 139 on Occupational Cancer. Geneva, 1974.

4. ICRP Publication 26. Recommendations of the International Commission on Radiological Protection. (1977).

5. Report of the Special Advisory Committee on Carcinogens. In: Fourth Annual Report of the Advisory Council on Occupational Health and Occupational Safety, 1981-82, pp.141-210.

6. One important source of such data in Ontario is the Ontario Cancer Registry maintained by the Ontario Cancer Treatment and Research Foundation.

7. Council Directive 79/831/EEC, September 18, 1979, amending, for the sixth time, Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

8. Identification, Classification and Regulation of Potential Occupational Carcinogens. 45 Federal Register, 5001 (1980).
See also: Advance Notice of Proposed Re-evaluation of Carcinogens Policy. 47 Federal Register, 187 (1982).

9. Council has given its advice on the constitution of such advisory groups in Advisory Memorandum 79-II, Concerning the Role of Advisory Committees in the Development of Regulations. Second Annual Report of the Advisory Council on Occupational Health and Occupational Safety, 1978-79, p.67-74.

10. Section 21(3) of the The Occupational Health and Safety Act reads as follows:

> 'For the purpose of this section, "new biological or chemical agent or combination of such agents" means any such agent or combination of such agents other than those used in one or more work places and included in an inventory compiled or adopted by the Ministry.'

In January 1981, the ministry announced the adoption of the Chemical Subatances Initial Inventory, together with the cumulative supplement, published by the Administrator of the Environmental Protection Agency of the United States of America.

Note

Bill 110, An Act to amend the Occupational Health and Safety Act, which received first reading on May 14th, 1982, proposes the re-enactment of section 21(3). The effect of this amendment would be that the provisions of section 21(1) with regard to new substances would not apply to the following:

(a) agents, whether in combination or not, used in one or more work places in Ontario on or before the 1st day of October, 1979; or

(b) agents, whether in combination or not, mentioned in an inventory compiled or adopted by order of the Minister.

11. For suggestions for the type of tests to be employed, see page 170 of the Report of the Special Advisory Committee on Carcinogens.

12. One metric tonne = 1.023 tons.

13. See, for example, the provisions with regard to substances to be placed on the market in quantities of less than one tonne, contained in: United Kingdom Interim Guide to Notification of New Substances. Health and Safety Executive; Department of the Environment. September, 1981.

14. Ibid. Substances Subject to Limited Announcement.

15. An example of a permit system for the regulation of workplace carcinogens is provided in Ordinance AFS 1981:8, concerning Hygienic Limit Values, issued by the Swedish National Board of Occupational Safety and Health, under the provisions of Section 18 of the Working Environment Ordinance (1977:1166).

Briefs Submitted in Response to the Discussion Paper

The Control of Workplace Carcinogens

ALGOMA STEEL

The Algoma Steel
Corporation, Limited

Sault Ste. Marie
Ontario, Canada
P6A 5P2

December 16, 1982.

Dr. J. F. Mustard,
Chairman,
Advisory Council on Occupational
Health and Safety,
400 University Avenue,
TORONTO, Ontario.
M7A 1T7

Dear Dr. Mustard:

The Algoma Steel Corporation, Limited would like to thank you for the opportunity of presenting our comments on the discussion paper entitled, "The Control of Workplace Carcinogens".

Algoma supports the need for control of exposure to workplace carcinogens. These comments are intended to be constructive towards the development of effective and practical carcinogen regulations.

We would be pleased to discuss these comments and any proposed regulations with you at your request.

Yours truly,

THE ALGOMA STEEL CORP., LTD.

RG Ryckman

R. G. Ryckman, C.I.H.,
Manager,
Industrial Hygiene Dept.

RGR/dj
Attach.

Algoma Steel
Industrial Hygiene Department

December, 1982

GENERAL

Algoma Steel supports the need for the control of occupational exposure to carcinogens. The general philosophy of categorization of chemicals by carcinogenic potential and regulation by category is acceptable. However, the mechanism proposed by the Advisory Council to categorize chemicals by carcinogenic potential requires considerable discussion and refining.

These comments are presented as a contribution to that refinement.

ADVISORY COMMITTEE

Algoma Steel opposes the establishment of an advisory committee on carcinogen regulations. Such a committee, comprised of representatives of various interest groups "involved in the area", may not have the necessary expertise to make difficult technical decisions based on scientific data. The committee will become a forum for adversaries to publicize non-resolvable, political positions. If issues are settled by democratic vote, emotionalism will most likely outweigh rationalism.

The appropriate branches of the Ministry of Labour should carry the full responsibility for developing the carcinogen regulations and not delegate that responsibility to an advisory committee. All interest groups must be given an opportunity to comment and the Ministry should then draft a regulation based on the best scientific evidence available.

The carcinogenic categorization of chemicals must be made on an individual basis with opportunity for comment from interested parties as is now the case in the development of all other regulations.

CATEGORIZATION OF CHEMICAL SUBSTANCES

The most important and contentious issue in the carcinogen regulation proposal is the carcinogenic categorization of chemical substances. The procedures proposed by the Advisory Council rely ultimately on the "feelings" (page 15) of the Advisory Committee. Conclusions concerning such an emotional issue as cancer cannot be rationally made based on subjective evaluation or "feeling". Incongruities such as the saccharin/tobacco issue are prime examples of subjective evaluation. The carcinogenic categorization of chemicals must be made with the utmost objectivity possible. The categories of carcinogen, suspect carcinogen and non-carcinogen as recommended by the Advisory Council cannot be defined much less applied.

Algoma recommends that carcinogenic categorization of chemicals be based on the results of scientific tests only, and not on the emotional-political "feelings" of a committee.

Categories based on test results might include the following:

Category I — Confirmed Human Carcinogen

- only those substances confirmed as carcinogenic in humans through recognized epidemiological methods will be included in Category I,
- use of Category I substances will be closely regulated,
- regulations should include mandatory epidemiological testing.

Category II — Positive Animal Tests

- substances showing positive test results for two different animal species using recognized test procedures are included in Category II,
- Category II substances should be subject to the same regulations as Category I substances with emphasis placed on epidemiological testing,
- substances showing non-positive epidemiological test results should remain in Category II.

Category III — Positive Short-Term Tests

- substances showing positive test results for two different short-term tests using recognized procedures are included in Category III,
- use of Category III substances should be regulated,
- regulations should include mandatory animal testing,
- substances showing non-positive animal test results should remain in Category III,
- indications of human carcinogenicity will place a substance into Category II irrespective of animal test results.

Category IV — Potential Carcinogen

- Category IV should include:
  1. all chemicals which have a structure similar to Category I, II or III carcinogens,
  2. chemicals considered by past experience to be a potential carcinogen,
  3. new chemicals which have no history related to carcinogenesis
- short-term testing should be required
- Category IV chemicals presently in use should be regulated,
- new chemicals should be tested before manufacture.

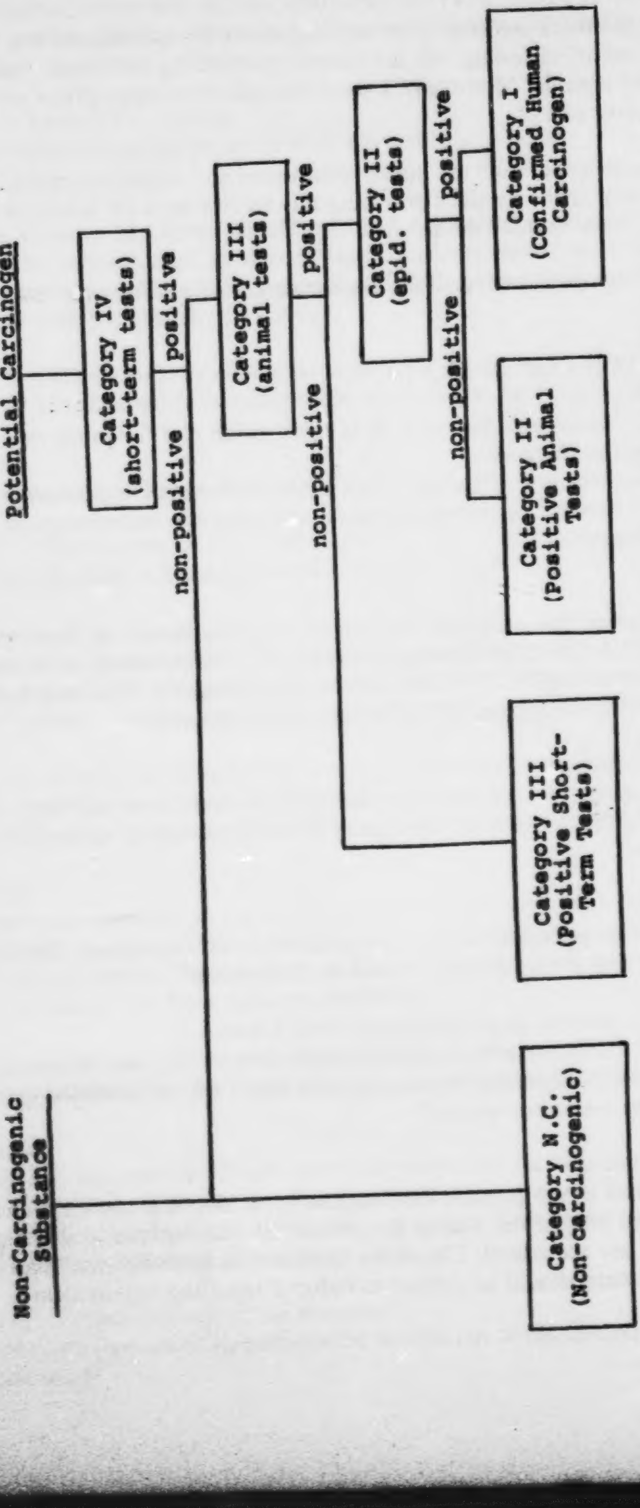
Category — Non-Carcinogenic

- Category "Non-Carcinogenic" should include:
  1. chemicals showing non-positive short-term results,

2. chemicals shown by long history not be carcinogenic.

- Category "Non-Carcinogenic" chemicals should not be regulated under a carcinogen regulation.

ALGOMA STEEL
PROPOSED SCHEME FOR CARCINOGENIC
CATEGORIZATION OF CHEMICAL SUBSTANCES


Potential Carcinogen
Category IV (short-term tests)
positive
non-positive
Category III (animal tests)
positive
non-positive
Category II (epid. tests)
positive
non-positive
Category I (Confirmed Human Carcinogen)
Category II (Positive Animal Tests)
Category III (Positive Short-Term Tests)
Category N.C. (Non-carcinogenic)
Non-Carcinogenic Substance

Category I, II, III and IV chemicals are subject to regulations specific to their respective categories.

Category "Non-Carcinogenic" chemicals are not subject to carcinogen regulations.

TESTING

The Advisory Council has recommended that manufacturers or importers of any new chemical be required to provide test results for possible carcinogenicity of that new chemical.

In order to ensure uniformity of carcinogenicity test procedures and adequate quality control of testing, all laboratories performing such tests must be accredited with the Ministry of Labour through some appropriate accreditation procedures.

Since carcinogenic tests are highly specialized and expensive procedures, the Ministry might consider providing this service on a fee basis, or provide a listing of accredited laboratories.

The Ministry should become the main resource of carcinogenic test information.

ISSUES FOR CONSIDERATION

Issue 1 — National & International Coordination and Cooperation in the Control of Carcinogens
Should the Ministry of Labour work with international organizations to establish a national carcinogen program and assemble information on chemical carcinogenicity?

Comment
Algoma agrees that a national carcinogen program should be developed. The Canadian Centre of Occupational Health & Safety seems to be the best suited for this purpose. The assembly of a carcinogenic data bank drawing from all available sources should be given high priority.

Issue 2 — Advisory Committee
Should an advisory committee be established with the responsibility for advising the Minister on all aspects of the regulatory program for carcinogens?

Comment
Algoma Steel opposes the formation of an advisory committee. This is dealt with above under the heading "Advisory Committee".

Issue 3 — Reporting Requirements for New Chemicals
Should full disclosure of possible carcinogenicity of any new chemical be required? Should reporting requirements be applicable to marketed quantities less than one tonne per annum?

Comment
Full disclosure of the possible carcinogenicity of any new chemical can be accomplished only if the testing procedures are standardized and testing laboratories are accredited. Chemicals marketed in quantities less than one tonne per annum should be subject to reduced reporting requirements.

Issue 4 — Testing Requirements for New Chemicals
Should all new chemicals be examined for carcinogenicity based on their chemical structure and relationship to known carcinogens?

Comment
Under Algoma's proposal, all new chemicals would be placed in Category IV. This would initiate a hierarchy of tests and a final categorization of the chemical.

Issue 5 — Testing Procedures
Should a standard testing program be developed?

Comment
Yes, the Ministry of Labour should establish a standard testing program based on the best scientific evidence. The procedures should be reviewed on a regular basis. In addition, laboratories performing these tests should be accredited with the Ministry of Labour.

Issue 6 — Classification of New Chemicals
Should all new chemicals be categorized according to proposed criteria?

Comment
This has been discussed under Issue IV.

Issue 7 — The Control of New Chemicals
Is the classification scheme proposed adequate?

Comment
This has been discussed under the heading Categorization of Chemical Substances. Permissible exposure limits should be set only after ample opportunity for public comment and examination of sound scientific evidence.

Issue 8 — Testing & Classification of Chemicals Not Considered New
Should priorities be set for testing chemicals which have not been adequately assessed for their potential carcinogenicity? Who should bear the cost?

Comment
All chemicals currently in use in Ontario, which have not been adequately assessed for their potential carcinogenicity, should be tested at the expense of the manufacturer. The Ministry of Labour should establish a priority listing to ensure that these tests are conducted.

Issue 9 — Control of Chemicals Not Considered New
How should chemicals not considered new be controlled by regulation?

Comment
A chemical not considered new should be subject to the regulations of its specific category. However, in existing manufacturing plants these regulations should be applied in a "phase-in" program. New plants should be subject to the regulations immediately.

Issue 10 — Epidemiological Surveillance
Should epidemiological surveillance be carried out when carcinogenic materials are used?

Comment
Under Algoma's proposal epidemiological surveillance would be required at the expense of the user for Categories I and II.

Issue 11 — The Provision of Information to the Work Force and to the Public
Should the chemical structure and potential hazards of any new substance be reported to the Joint Health & Safety Committee?

Comment
The chemical structure of any new substance should be submitted to the Ministry of Labour by the manufacturer. The release of proprietary information to the Joint Health & Safety Committee would provide no additional protection for the worker since these committees are usually not qualified to interpret chemical information. Results of carcinogenic testing and the final categorization of the chemical should be released to the Joint Health & Safety Committee. The confidentiality provisions of Section 34(1)(b) of the Act should apply.

Issue 12 — Penalties for Non-Compliance with the Regulation
Should penalties for violation of carcinogen regulations be in excess of those currently available under Section 37(1) of the Occupational Health & Safety Act?

Comment
Penalties for non-compliance with the carcinogen regulation in excess of those provided by Section 37(1) of the Occupational Health & Safety Act are not logical. Three carcinogens (coke oven emissions, vinyl chloride, and asbestos) are now regulated and therefore covered by Section 37(1) of the Act. There can be no justification for increased penalties for other carcinogens.

Efforts should be concentrated on control of exposure and not punitive action.

The suggestion for increased penalties for non-compliance with a carcinogen regulation reflects the emotionalism of the carcinogen issue.

Issue 13 — Research
Should provision be made for the relaxation of regulatory requirements for research purposes?

Comment
Specific regulations should be written for the use of carcinogenic materials in research work.

BASF Canada Inc.

BASF

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November 11, 1982

Dr. J.F. Mustard
Chairman
Advisory Council on Occupational
Health and Occupational Safety
400 University Avenue
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

As the designated contact person for Canadian ETAD affiliated companies I am attaching ETAD's comments on the Discussion Paper on Control of Workplace Carcinogens.

Should you wish to communicate any messages to ETAD, please send them to my attention.

Yours truly,

BASF CANADA INC.

Jack Gess
Product Safety Co-ordinator

Encl.

JG/at

ETAD comments on Discussion Paper on Control of Workplace Carcinogens

November, 1982

The Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry (ETAD) is an international association, based in Basel, Switzerland, which was formed to coordinate the efforts of the manufacturers of organic colorants to lower any adverse effects of these products on the environment and to provide the best possible protection for the users and consumers of these products. ETAD seeks to aid and co-operate with governmental departments, agencies and any other public institution concerned with these matters. The ETAD membership, presently 28 companies, represents over 80% of world-wide organic colorant production (excluding COMECON and China).

The following ETAD affiliated companies are active in the Province of Ontario:

- Atlantic Chemical Corporation
- BASF Canada, Inc.
- Bayer Canada, Inc.
- CIBA-GEIGY Dyes Limited
- CIL, Inc.
- Crompton & Knowles Corporation
- Hoechst Canada, Inc.
- Sandoz Canada Limited.

ETAD's comments are limited to the Advisory Council's Discussion Paper since the referred to *Report of the Special Advisory Committee* was not received by our association.

Following careful study of the Advisory Council's Discussion Paper, ETAD endorses (page references refer to the Discussion Paper):

1. The objective of establishing a framework for control of exposure to workplace carcinogens (page 3);

2. Recognition by the Advisory Council that a zero risk approach is unrealistic (page 4);

3. Recognition by the Advisory Council of need to seek harmonisation at federal level (page 8). The need for international harmonisation is also important;

4. Recognition by the Advisory Council that the carcinogenic potency of a substance must be taken into account in any risk assessment, and in determining appropriate regulatory controls (page 11);

5. Proposal to accept relevant information developed outside Canada (pages 12-13).

ETAD, in general, endorses the submission made by CCPA (The Canadian Chemical Producers' Association); however, our association would like to make the following specific comments on the Discussion Paper:

1. Page 2 — The Advisory Council explains their rationale in singling out the regulation of carcinogenic hazards. This is without doubt an important area of concern. However, the public perception of the extent of workplace carcinogenic risks is grossly exaggerated (see Doll and Peto review), and regulatory efforts to secure greater workplace safety should seek to keep these risks in proper perspective. Furthermore, a mechanism for regulating carcinogens in the workplace is already provided by the Occupational Health and Safety Act of 1978.

2. Pages 9-10 — The first paragraph under Item (II.1) implies that consideration of the regulatory approaches of other jurisdictions, including U.S., leads to the conclusion that there is a *general acceptance* that *all* new chemicals should be screened for carcinogenicity.

Under the 6th Amendment, EEC requires certain levels of toxicological testing based on production volumes. Chronic studies (two year) are not required until a total manufacturing volume exceeds 1,000 tons/year. Chronic studies, therefore, are not required as a matter of course.

The above implication is also misleading with respect to U.S. philosophies. There are *no* proposed or finalised regulatory *initiatives* issued under either the Toxic Substances Control Act or the Occupational Safety and Health Act *which require testing* of new chemicals for carcinogenicity prior to manufacturing or marketing in the United States.

In the United States, under TSCA, the producer/importer of the new chemical must demonstrate that it does not present an unreasonable risk to human health and the environment. Since "risk" is a function of magnitude of exposure as well as of the toxic characteristic of a chemical, extensive testing is not suggested if the exposure is minimal.

Furthermore, if a PMN (Premanufacture/Market Notification) based on a risk assessment had been filed and accepted in other juriedictions (e.g., EEC or U.S.), then no further testing should be required for a new chemical introduced in Ontario.

3. Pages 12-16, 31 — The Advisory Council outlined the approach that the new chemical substance review and testing process could take. To understand the potential impact of this scheme, consider the following:

Average cost of testing per product to implement the proposed testing scheme is projected to be $430,000. A dyestuffs manufacturer can only anticipate the total profit over the lifetime of a product (ten years) within the province to be $100,000. From the manufacturer's standpoint, if the upfront estimated cost to potentially realise this return in Ontario is $430,000/product, then new products will not be introduced into the province.

4. Pages 12-17 — The proposals regarding classification of carcinogenicity are unsatisfactory. ETAD regrets that it is proposed to set up a unique approach for Canada rather than to seek to collaborate in an international effort. Detailed consideration should be given to the availability of sufficient expert oncologists required to undertake the massive task proposed. Pursuit of the proposed approach is likely to result in most products being placed in Category II and some in Category I, leaving the regulatory authorities with the virtually impossible task of introducing appropriate control measures.

5. Page 13 — The Advisory Council proposes that substances be assessed as used because of the likely presence of impurities. ETAD agrees that any hazard assessment should take into account the possible influence of impurities on the properties of the substance. However, it would not be practicable nor sensible to conduct long-term animal testing on commercial products of ill-defined composition. Such testing has been undertaken in the past and has led to considerable confusion in the interpretation of the results. Although it may be appropriate to carry out certain tests with the product as used it is ETAD's view that expensive long-term testing can only be justified if it can lead to an unequivocal conclusion regarding the carcinogenicity or "non-carcinogenicity" of the primary component. This result should then be supplemented by an appraisal of the likely influence of impurities. Only in this way is it possible to enable cost-sharing by those companies involved, and to recognise that for many chemicals the range of impurities can vary from batch to batch, and even more so with time during the course of process improvement.

6. Page 13 — The Advisory Council proposal that substances should go directly into long-term animal testing, regardless of the quantities to be used, on the basis of similarity to a known carcinogen, or tissue accumulation is not realistic.

The use of structural activity relationship can be of value in determining testing priorities but is not yet a sufficiently developed technique for predicting carcinogenic potential. It is further questioned which group will determine whether the chemical structure of the new substance is structurally related to a known carcinogen. Will this be the Ministry of Labour or the manufacturer? Will a structural relationship to a known non-carcinogen place the substance in Category III automatically? Is this what is meant by the term 'variants' on Page 15? Will the same criteria be used to identify 'variants' as well as structural analogies to known carcinogens? What substances are "known" carcinogens?

What method (e.g. bioaccumulation, partition coefficient, etc.) and what objective criteria (e.g. log P > 10) will be used to determine whether or not tissue accumulation will occur? How is this factor related to carcinogenicity?

The proposal that there should be any automatic progression to long-term animal testing must be rejected, in particular if it is made on such flimsy basis as structural activity relationship. The identification of a need for long-term animal tests must be preceded by a risk assessment taking into account exposure levels, and any other toxicological data, e.g. response in short-term tests, must also be duly taken into account. Before allocating resources to long-term testing the question must be asked. "Even if the result is positive, would this product pose an unreasonable risk under its conditions of use?"

7. Page 14 — For similar reasons to those given under 4. it is not realistic to proceed automatically from positive or conflicting short-term test results to long-term testing.

8. Page 18 — The Discussion paper's concept of evaluating and categorising old chemicals within a five year period does not appear to be feasible. We estimate that if the worldwide laboratory testing capabilities were devoted solely to the evaluation of those old chemicals which are likely to be placed in Category II initially* the entire testing program would take over *eighty years* to complete at a cost of *$15.6 billion* (1982 dollars). This, therefore, also assumes the new chemicals testing program is discontinued.

The proposal requires the Ministry to make a determination of the potential carcinogenicity for substances on the EPA list (which now numbers over 58,000 chemicals) and those sold in Ontario which are not on the TSCA list. Does the Ministry have the staff to collect/review and evaluate the known data on over 60,000 chemical substances? Once prioritised, how does the Ministry intend to determine which of many possible international manufacturers of identical chemicals should incur the testing burden?

As we view it, the current discussion paper leaves only two options open to the dyestuffs manufacturers:

1. Stop manufacturing and/or marketing in Ontario, or
2. Pass the cost of such testing on to the Ontario consumer.

For the dyestuffs manufacturer, this would require a minimum of a 5-10 fold price increase for all products sold in the Province of Ontario. This would place the Ontario dyestuffs consuming industry at a considerable competitive disadvantage as compared with their competitors outside the Province.

9. Page 19 — The proposal to subject existing chemicals to the same testing and classification procedures as employed for new chemicals, when they are to be used in a newly-constructed plant, is opposed by ETAD as its effects would be counter to the objectives of improved worker safety. Newly constructed plants normally incorporate better product handling facilities and offer the worker a better environment involving lower exposure to chemicals.

10. Page 27, issue 9(3) — The proposal to extend the requirements for new chemicals also to existing chemicals after a period of 5 years is not sensible. ETAD does not claim a blanket exemption from testing for existing chemicals. However, demands for testing must recognise the financial and test capacity limitations. Above all they should take full account of the history of human experience in the use of the respective substances.

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*The above figures were derived assuming only 60% of all old chemicals would initially be placed in Category II.

11. Page 28, issue 11.1 — ETAD supports efforts to ensure that the workforce is well informed regarding potential hazards from chemicals in the workplace. The provisions in the regulations should reflect the experience that for chemicals the disclosure of chemical identity can rarely contribute to improved health and safety in the workplace. For this reason a manufacturer should only be obliged to disclose, to qualified experts, a confidential chemical structure under exceptional circumstances.

In closing, and in addition to the foregoing comments, ETAD would summarise as follows its views on the most effective approach to the control of occcupational carcinogens:

1. A broadly-based approach is required, which maintains carcinogenic risks in a sensible perspective with other risks;

2. The provisions for carcinogens should be consistent at international level in terms of

- substances recognized as carcinogens,
- control measures, exposure levels, etc.

3. Greater emphasis should be placed on achieving overall reductions of workplace exposure to all chemicals, i.e. the use of good working practice. The priority for product testing should then be viewed in the context of the lower practical exposure levels achieved.

Only in this way can the testing needs be brought more into line with the availability of testing resources and the commercial realities. Inherent in this approach is the acknowledgement that, however thoroughly tested, chemicals can pose unrecognised hazards and the best prophylactic measure is to avoid unnecessary exposure.

4. Less emphasis should be placed on structural activity relationship and unvalidated short-term testing procedures as a means of predicting carcinogenicity. The current state of knowledge still limits the value of these approaches for drawing firm conclusions.

Bayer

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Dr. J.F. Mustard
Ministry of Labour
Occupational Health and Safety
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Pointe Claire, October 22, 1982.

Re: Discussion Paper Carcinogens at the Work Place

Dear Dr. Mustard:

We have been advised by the Canadian Urethane Manufacturers' Association sometime ago of the Advisory Council's discussion paper on identifying and regulating potentical carcinogens.

We have already submitted the attached information to the Canadian Manufacturers' Association, but felt that in view of the time elapsed we should acquaint you directly with the report from our parent company in Europe.

The matter has been submitted to the Environmental Protection Department of our parent company in Germany, BAYER AG, who have submitted to us a set of documents, which we are enclosing herewith.

We were, furthermore, advised of BAYER's comments as follows:

"According to the discussion paper by the Ontario Ministry of Labour, the substances under review are to be classed into three categories:

Also in the European economic community carcinogens are to be grouped into three classes, however, contrary to the Canadian proposal, these refer directly to the observed effects on humans or in animal tests. The classification will be made according to the following criteria:

1. human proved
2. animal proved
3. suspected (resp. other results)

The category III ("no carcinogens"), as per the Canadian proposal does not exist in the European Common Market and will also not be applied in the United States.

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encl.:

et "Bayer" sont des marques déposées de Bayer Allemagne

nature

The above mentioned sub-division is supported also by the scientific community. Enclsoure (1) attached herewith is Monograph 3 of the ECETOC, dealing with the classification of carcinogen matters, the determination and the minimization of risks in handling them. Since this document deals with the principle consideration on the subject of carcinogens, we suggest that it be made available to the respective government authorities.

Dealing with carcinogens has already been settled in the German Federal Republic. This regulation contains a division into 3 classes. The regulation of dangerous substances in the work place contains rules on reporting controal measures, occupational health controls and work time limitation. However, only those substances are considered carcinogen which are listed. Their classification is done by scientific gremium.

As enclosure (2) we are attaching the inofficial translation of regulations on carcinogens from the work rules. We suggest that you also make this document available to the Canadian commission."

As mentioned above, we are enclosing herewith an article (Appendix 1) entitled ECETOC "Risk Assessment of Occupational Chemical Carcinogens", and appendix 2 "Carcinogenic Materials", List of Carcinogenic Materials Field of Application.

We remain,

Yours very truly,

BAYER (CANADA) INC.

H.F. Rosendahl

H.F. Rosendahl

European Chemical Industry
Ecology & Toxicology Centre

January, 1982

Monograph No. 3

Risk Assessment of Occupational Chemical Carcinogens

TABLE OF CONTENTS

FOREWORD 53

SUMMARY 53

A. INTRODUCTION AND DEFINITIONS 54

B. HAZARD IDENTIFICATION 56

B.1. Classification of Chemical Carcinogens 56
B.2. Sequence of Steps for Establishing the Presence or Absence of Carcinogenic Potential 57

C. RISK ESTIMATION 61

C.1. Evaluation of Carcinogenic Potency 61
C.2. Evaluation of Exposure-Related Factors 68
C.3. Outcome of Risk Estimation 69

D. RISK LIMITATION 70

APPENDICES

1. Conclusions Based on Short-Term Tests for Carcinogenicity 71
2. Details of Factors Influencing Exposure 73
3. Members of Task Forces 75
4. List of Various ECETOC Documents 76

FOREWORD

The ECETOC Monograph "A Contribution to the Strategy for the Identification and Control of Occupational Carcinogens", was published in September 1980. This set out specific recommendations for the control of occupational carcinogens using the general principles which are applied to the identification and control of any toxic hazards. The monograph was well received as a useful contribution to defining the issues and principles which are key contributors to the strategy of identifying and controlling chemical carcinogens, and to date over 2,200 copies have been issued.

In the current Monograph "Risk Assessment of Occupational Chemical Carcinogens", is reported the work of two further Task Forces completing the study of Hazard Identification and proposing an approach to the very difficult subject of Risk Assessment which it is hoped will be helpful to all those in industry, trade unions, government, international organisations and universities who are responsible for, or are concerned about, the protection of people from occupational carcinogens. As the studies developed it became apparent that the terminology used in the previous Monograph to describe the three-stage approach should be modified, and in this Monograph the subject is reported under the headings Hazard Identification, Risk Estimation and Risk Limitation.

ECETOC has published a number of papers on current toxicological and ecotoxicological issues, a list of which is given in Appendix 4. Copies are available on application to the Executive Secretary.

A. ROBERTSON
Director, Imperial Chemical Industries Limited
Chairman, ECETOC

SUMMARY

In a previous Monograph ("Contribution to the Strategy for the Identification and Control of Occupational Carcinogens", September 1980) a three-stage process for identifying and controlling occupational chemical carcinogens was proposed, and a classification of chemical carcinogens was described as part of the first (essentially qualitative) stage, Hazard Identification, which is completed in this Monograph by an account of the sequence of steps necessary to establish the presence or absence of carcinogenic potential. Then follow details of the second stage, Risk Estimation, in which are taken into account the mode of action of carcinogens, the carcinogenic potency and the factors relating to human exposure. The carcinogen is categorised as being of high, medium or low potency, and by relating this to the exposure conditions the risk is characterised in as quantitative a manner as possible.

Hazard Identification and Risk Estimation should be carried out by a group comprising toxicologists and other experts from all necessary disciplines.

In the final (Risk Limitation) stage the information from Risk Estimation is considered, together with technological, social and economic factors, by a wider group of the parties ultimately concerned with implementing the recommendations made to control the risk, plus experts from the Risk Estimation stage. This group recommends exposure levels or working conditions such that the carcinogenic risk is controlled by means which are technologically feasible and take into account the social and economic consequences of the measures proposed.

A. INTRODUCTION AND DEFINITIONS

A few terms which it is essential to clarify at the outset of any discussion of risk assessment and carcinogenicity are defined below:

Toxicity is the inherent property of a chemical to cause an adverse biological effect.

Cancer is a malignant neoplasm with autonomous growth and certain pathological characteristics which include atypia, invasive growth and, frequently, metastasis.

Carcinogenic potential is the inherent property of a chemical which enables it to produce a cancer under appropriate conditions.

Carcinogenic potency is the magnitude, with respect to dose, of the carcinogenic activity of a chemical in the species under consideration.

Carcinogenic hazard is the existence of a situation with a potential for causing cancer.

Carcinogenic risk is the probability that a certain population under specified conditions of exposure will develop an increased incidence of cancer. (This risk can only be estimated; hence the term Risk Estimation used in this Monograph.)

In the ECETOC Monograph No. 2, three stages in the overall process of risk assessment for occupational chemical carcinogens were noted. As work on the present Monograph progressed it became clear that the three stages were more appropriately entitled:

Hazard Identification
Risk Estimation
Risk Limitation

in line with current usage of the terms "hazard" and "risk". Such nomenclature is adopted in this Monograph, in which the scientific and technical bases for Hazard Identification and Risk Estimation are presented in some depth. Risk Limitation, of which the above scientific and technical input is only a part, is not examined in any detail.

Hazard Identification.
The aim of this first stage in risk assessment is to establish qualitatively whether a carcinogenic hazard exists. A chemical is classified, according to the evidence concerning its carcinogenic potential, as a Proven, Putative or Questionable Human Carcinogen.

To achieve this classification, information on carcinogenic potential needs to be developed in a sequence of steps as described in section B.2.

Such a classification is essential for identifying Proven and Putative carcinogens for which risk assessment is necessary. Classification as Questionable in the early stages of Hazard Identification indicates that more work is required to permit a re-classification into one of the other classes, or a decision that for practical purposes the chemical should be considered as a non-carcinogen for humans — see section B.1.

Risk Estimation
Once a carcinogenic hazard (i.e. situation with a potential for causing cancer) has been identified it is necessary to quantify as far as is possible the carcinogenic potency of the substance and the factors relevant to human exposure at the workplace. By relating these, the risk is characterised in as quantitative a way as possible. Both the collection of the necessary information and the characterisation of the risk are considered to constitute the Risk Estimation stage.

Risk Estimation is feasible only for Proven and Putative Human Chemical Carcinogens because by definition there is insufficient evidence for chemicals in the Questionable class. In making a Risk Estimation there is a practical requirement to distinguish between carcinogens of widely-differing potency in spite of the many limitations in the expression of such potency. This can be achieved by a group of experienced scientists capable of assessing the various factors involved. By relating the potency of a carcinogen to that of other Human or Putative carcinogens it can be categorised as of high, medium or low potency. This process is described in section C.1. Factors necessary for assessing human exposure to the chemical at the workplace, also necessary in Risk Estimation, are detailed in section C.2. It is emphasised that very rarely is sufficient evidence available to enable a Risk Estimation to be expressed numerically in such terms as "a 1 in 10^6 risk of cancer at an exposure of 10 ppm". The question therefore becomes more one of expert judgement than of mathematics. This is why the term Risk Estimation is used.

Hazard Identification and Risk Estimation are tasks for an experienced group of toxicologists, and other experts from all necessary disciplines.

Risk Limitation:
The information from the Risk Estimation stage is considered, together with important additional factors such as the social and economic consequences, technological feasibility, etc, and a final recommendation for an exposure level and/or working conditions is made.

This is a task for a group comprising representatives of the parties ultimately concerned in implementing the recommendations made to the control the risk, plus experts from the Risk Estimation group.

Although this Monograph deals with chemical carcinogens at the workplace, much of the material is generally applicable to the assessment of public risk from chemical carcinogens, the sections dealing with classification, sequence of steps for the identification of carcinogenic potential, and estimation of potency being particularly relevant.

B. HAZARD IDENTIFICATION

To identify the carcinogenic risk which might arise from exposure to a chemical, the carcinogenic potential of that chemical must first be carefully assessed. Carcinogenic potential (not to be confused with potency) is the inherent property of a chemical which enables it to produce a cancer under appropriate conditions. It is revealed only by appropriate observations of the carcinogenic effect on humans or in suitable experimental systems. Accumulated data may allow the chemical to be classified into one of a number of classes. A classification system, and the sequence by which data on carcinogenic potential are developed, are described in the following sections.

B.1. CLASSIFICATION OF CARCINOGENS

Carcinogens can, according to the extent and quality of the evidence available, be classified as follows.

Proven Human Chemical Carcinogen:
"A proven human chemical carcinogen is a substance for which a causal relationship has been established between previous exposure and the occurrence of malignant neoplasms in man".

Putative Human Chemical Carcinogen:
"A putative human chemical carcinogen is a clearly-defined chemical substance which causes malignant neoplasms in adequate animal experimentation, under exposure conditions which correspond to those in man or where the relevance of the exposure conditions can be deduced".

Questionable Human Chemical Carcinogen:
"A questionable human chemical carcinogen is a clearly-defined chemical substance for which there is incomplete evidence of carcinogenicity, which is based on either (a) observations in man which are suggestive, but do not allow a firm conclusion of a causal relationship between previous exposure and the occurrence of malignant neoplasms; or (b) findings obtained in animal experiments in which the experimental model is not appropriate to conditions in man and therefore the result cannot be regarded as relevant; or (c) positive findings in at least two standardised short-term tests, with unrelated end-points, which have been verified as useful for screening for carcinogenic potential".

Such a classification is important since risk assessment is possible only with chemicals in the Proven and Putative classes. The same principles should be adopted for both Proven Human and Putative Human carcinogens, but such a classification emphasises that any well-established, relevant differences between man and test animals must be taken into account during this assessment of chemicals in the Putative class and such chemicals cannot automatically be regarded as being in the Proven Human class. Classification of chemicals in the Questionable class means that, by definition, carcinogenic risk assessment is not possible. For such chemicals more evidence should be collected so that they can be reclassified into the Human or Putative class, or considered as a Human Chemical Non-carcinogen (see Monograph No. 2: "An ultimate proof of non-carcinogenicity is impossible. However, a clearly-defined chemical substance which has consistently shown negative results in adequate studies in man, or adequate animal experimentation, should be considered as a Human Chemical Non-carcinogen for practical purposes").

This classification of carcinogens should be carried out by a group of experienced scientists. Because of the number and variety of factors which have to be taken into account, no rigid procedure for the classification can be laid down and each chemical has to be dealt with individually.

B.2. SEQUENCE OF STEPS FOR ESTABLISHING THE PRESENCE OR ABSENCE OF CARCINOGENIC POTENTIAL OF A CHEMICAL

This section is intended to give guidance to those who need to establish evidence as to whether a substance is a chemical carcinogen.

B.2.1. Introduction

A wide range of techniques contributes to the assessment of carcinogenicity. The complexities of the toxicological factors, and others such as limited availability of expertise, resources, time, etc, and their inter-relationships, make necessary a sequential approach with progressive accumulation of data on which judgements of carcinogenic potential can be made.

The precise sequence of steps in evaluating the presence or absence of carcinogenic potential may vary from chemical to chemical, and many interrelated considerations influence the choice of steps. The conditions of human exposure, the existence of other priorities, and legal or economic considerations may interfere with purely toxicological decisions to move from one step to the next. Nevertheless, this case by case approach is also justified for toxicological reasons, amongst which are:

a) the large differences in carcinogenic properties and potency of chemicals,
b) the variety of mechanisms of cancer induction,
c) the diversity of tumour responses in different species and tissues,
d) the differences, from one chemical to another, in the relevance of the experimental models used for extrapolation to man.

Thus to implement any rigid, standardised or obligatory sequence of steps may lead in some cases to the performance of inappropriate studies, while in other cases key studies would not be undertaken. Therefore, to preserve indispensable flexibility this document provides general principles rather than specific recommendations, as guidance for choosing the sequence of steps most appropriate for a particular chemical.

B.2.2. Guidelines

The evaluation of the presence or absence of carcinogenic potential is not an isolated process, but is part of an overall evaluation of the toxic properties of a chemical. As the knowledge of these properties accumulates, more or less well-defined phases of advancement in our understanding of the carcinogenicity (or non-carcinogenicity) of a substance can be identified. These phases are logically, but not necessarily sequentially, related and in general provide increasing degrees of confidence in decisions taken about carcinogenic potential.

For each phase a survey is given of: the studies required, the reliability of the results so obtained for the assessment of carcinogenic potential (given in **bold**); and the role of these data in preparing for the next phase.

B.2.2.1. Pre-experimental phase.

Before experimental studies are started it is essential to carry out a comprehensive evaluation of the literature. In the absence of published evidence of carcinogenic potential, the substance under consideration should first be examined for structural features which might relate it to compounds with or without carcinogenic potential.

It should be emphasised that with our present knowledge, the use of structure-activity relationships to predict carcinogenic potential is of limited reliability. Therefore, at this phase any assessment of carcinogenic potential can have only a limited value.

Structural considerations may help in choosing suitable experimental designs, e.g. it is important that the chemical class or structural group to which a substance belongs should be taken into account in deciding which short-term carcinogenicity screening tests should be used.

B.2.2.2. Phase of carcinogenicity and toxicity screening.

In this phase, information will be acquired about the activity of a chemical in short-term tests for predicting the presence or absence of carcinogenic potential (see Appendix 1), and about relevant aspects of its toxicological profile.

Many short-term techniques with different methodologies and different end-points have been developed; others are still under development. They involve the investigation of effects on genetic material (e.g. gene mutation, chromosome aberration, unscheduled DNA synthesis, sister-chromatid exchange), cell transformation, and the induction of preneoplastic or neoplastic lesions. Criteria for selecting valid short-term tests and for drawing conclusions from the results were published in the earlier Monograph and are given here in Appendix 1.

It should be recognised that the majority of the methods available have not been properly assessed for their predictive value in detecting carcinogenic potential. Therefore, the attempts which have been made to arrange these methods into hierarchical tier-systems should not be relied upon.

At this phase other aspects of the toxicological profile may be useful, e.g. data on bioavailability, metabolism, cellular or functional targets (e.g. hormone balance and immunological status) and species differences. Such assessments of toxicity should preferably be made after repeated administration and with a knowledge of dose-effect relationships. These data, together with the results of short-term tests for carcinogenicity, are used in the assessment of carcinogenic potential, and in the development of views on the need for investigations in the next phase.

This screening phase may allow the chemical under consideration to be classified as a "questionable human chemical carcinogen". The quality of the assessment of carcinogenic potential possible at this phase depends on the consistency of all the available results.

While consistently negative results in the carcinogenicity screening phase do not constitute proof of non-carcinogenicity, further studies may not be required unless exposure criteria (intensity, frequency and duration of exposure; extent of absorption; other properties of the chemical; its importance, etc) indicate the need for greater reliability in assessing the presence or absence of carcinogenic potential.

When consistently positive indications of carcinogenic potential are obtained in this phase, consideration should be given to carrying out long-term animal studies.

If an unconfirmed result is obtained, expert judgement is required to decide on an appropriate course of action (see Appendix 1). Under normal circumstances, data on the next phase are required to allow a more accurate assessment to be made.

Factors other than carcinogenic and toxicological properties may rule out the need to go to the next phase of testing. For example, a variety of reasons may lead to complete withdrawal of a chemical from the market or to stopping the development of a new chemical. On the other hand, a decision not to go to the next phase of testing may be taken if the probable human exposure to the chemical is insignificant in relation to its assumed carcinogenic potential.

The design of adequate long-term animal experiments should be based upon essential data that are being collected during this phase. These include: exposure conditions, choice of the appropriate route of administration, selection of species and the choice of the highest dose level.

B.2.2.3. Phase of long-term animal experimentation

Short of adequate epidemiological data, this phase represents the ultimate stage of establishing the presence or absence of carcinogenic potential of a chemical. Model systems should be used which either mimic closely the human situation, or have demonstrable relevance to it. The animals, of the same strain as those used in the long-term carcinogenicity study, should be monitored for long-term general toxic effects. This monitoring, covering the range of dose levels used in the carcinogenicity study, can be indispensable in interpreting the observed response in target organs.

The different requirements of carcinogenic and chronic toxicity studies can lead to very different protocol designs. This is especially true in setting the highest dose level, and the number of animals to be used.

At the end of this phase an assessment of the carcinogenic potential of a chemical substance can be made on the basis of all available data.

B.2.2.4. Phase of evaluation of observations in man.

The collection and evaluation of observations on people exposed to chemicals is the only method which provides unequivocal evidence of the carcinogenicity of chemicals to man. While the finding of such evidence on a particular chemical carcinogen means that the opportunity of preventing cancer has been lost for some of the population at risk, the identification of a "proven human chemical carcinogen" provides the opportunity to prevent the occurrence of future cases once suitable control measures are taken. Observations in man are also valuable for confirming the lack of carcinogenic activity, and for evaluating the effectiveness of the preventive measures taken against a chemical carcinogen.

Human data related to chemical carcinogenesis range from the incidental recognition and accumulation of individual cases in an exposed population to formal epidemiological studies. The accumulation of individual cases may sometimes constitute convincing evidence, e.g. for those chemical carcinogens inducing otherwise rare types of cancer or cancers with an unusually short latency time.

The formal epidemiological studies comprise case-control studies (or retrospective studies) and cohort studies. Cohort studies may be historical or prospective. In the former, the vital status of people exposed in a sufficiently remote past is established and cancer incidence is compared with that of unexposed groups. The latter studies start with an unaffected group which is followed-up during a sufficiently-long period of exposure. It is obvious that prospective cohort studies are not suitable for identifying the carcinogenic potential of "new" chemicals. If cancer is detected, exposure has already taken place for quite some time because for most chemically-induced cancers in man the latency period is a significant proportion of the life-span. However, prospective studies are well suited to check the adequacy of protective measures taken against a known carcinogenic risk.

The different types of epidemiological studies are not equally reliable. Whenever possible, cohort studies with age-, sex-, and time-adjusted standard mortality ratios are preferred. The value of these studies is highly dependent on the accuracy of the exposure and health data, as well as on the suitability of the control group. However, they seldom demonstrate unambiguously a cause-effect relationship between exposure and the induction of neoplasms. By the laws of probability a small but statistically-significant excess of at least one type of cancer may randomly occur when comparing the mortality pattern of two groups. In most cases excess cancer incidence can confidently be attributed to a selected chemical if this excess is consistent, specific and clearly relate to particular exposure conditions. Any conclusion about a possible cause-effect relationship is often confounded by the fact that human groups are usually exposed to more than one chemical. In most cases only correlations which provide a lead for further examination can be established. Additional toxicological data may be needed to identify individual substances responsible for an observed carcinogenic effect in people exposed under complex physical and chemical environmental conditions.

If a clear-cut cause-effect relationship can be established at the end of this phase, the chemical can be classified as a "Proven human chemical carcinogen" and the data can be used directly for Risk Estimation.

C. RISK ESTIMATION

C.1. EVALUATION OF CARCINOGENIC POTENCY

C.1.1. Introduction

Carcinogenic potency is the magnitude, with respect to dose, of the carcinogenic activity of a chemical in the species under consideration. In the process of estimating the carcinogenic risk of chemicals to man, the determination of carcinogenic potency to man and the conditions of exposure in particular circumstances are the most important elements. It is stressed that carcinogenic potency can be asssessed only for chemicals classified as Proven or Putative Human Carcinogens (see definitions in section B.1).

Human data suitable for potency estimation can be obtained only when reliable exposure data and the health status of the exposed individuals are known with the necessary precision over a sufficient period of time. For the majority of chemicals the carcinogenic activity can be assessed only in animal experiments in which malignant tumours are induced under circumstances of exposure that are relevant to the human situation, or where this relevance can be deduced. There are limitations in using such experiments for potency estimations, the main one being the difficulty of extrapolation from experimental species to man. Carcinogenic activity may be markedly influenced by species-specific characteristics, some of which, such as metabolism and kinetics, will be discussed in more detail below.

In spite of these limitations in the expression of potency there is a practical requirement to make a distinction between carcinogens of widely-differing potency. This can be achieved by considering the various factors discussed here and expressing the potency of a carcinogen as high, medium or low in relation to that of other Proven or Putative Human Carcinogens.

C.1.2. Terms for Expressing Potency

The terms used to express the potency of any toxic activity are a function of dose and intensity of effect. In the case of carcinogens the expression of both dose and intensity, or incidence, is so complex as to preclude the calculation of a simple numerical index. The ideal expression of dose would be the concentration, integrated over time, of the ultimate carcinogen at the critical target site. This expression of dose is dependent on the frequency, magnitude, duration and route of exposure and the interaction of these factors with metabolic processes and kinetics which affect the concentration at the specific target site. The expression of all these factors in a simple numerical dosage figure which would permit direct comparison between different carcinogens and species is not currently feasible. The parameters needed for expressing cancer incidence and intensity in animals include the proportion of tumour-bearing animals, multiplicity of tumours in one organ or animal, time to development of tumours, cell-type affected, and the growth rate and behaviour of the cells. Combining them into a single figure is an inaccurate over-simplification. Thus a function of dose (an independent parameter), and intensity and incidence (dependent parameters) cannot be expressed in a simple way allowing direct mathematical comparison of potency. Similar problems in expressing the exposure and response of humans limit the utility of any simple numerical index derived from epidemiological studies.

C.1.3. Human Data as a Basis for Potency Evaluation

Data obtained from observations on man are closest to ideal for grouping chemicals according to potency. However, these data are frequently deficient in precise information required to determine the dose, duration of exposure, and incidence.

For Proven Human Carcinogens only retrospective data-gathering is possible and in most cases the available information consists, at best, of an accumulation of case histories. For potency estimation from retrospective studies it is necessary to relate the magnitude of effects in man to the duration and levels of exposure to the particular carcinogen. However, accurate historical exposure measurements and clearly-identifiable increases in cancer in man are only rarely available. Indeed, even when an increased incidence of cancer has actually been identified, the exposure conditions occurring many years previously have to be traced back because of the long latency of chemically-induced cancer. Failure to recognise the importance of quantitative exposure data in earlier times has led, inevitably, to a general paucity of data regarding the exposure of the worker and other populations. The situation is somewhat different in occupational settings today, where worker exposure is more frequently recorded accurately. It should be noted that the data from human epidemiology is often less precise than that from animal experiments. The conditions of exposure of workers, their age, and the variety in their genetic background are quite different from the steady and well-controlled exposure conditions and genetic background in animal experiments. Moreover, the magnitude of the health effects in man is known with less accuracy than in experimental animals. Indeed, in man the cause of death is in most cases not confirmed pathologically even though the registration of mortality from cancer has been improved by the organisation of cancer registries. Because human exposure levels are usually rather low in comparison to those in animal experiments, increases in cancer incidence may be small and may remain undetected, even with easily-recognised tumour types. When the background incidence of the observed tumour is relatively high, and the type and site are common, it may be difficult to notice any small increase in this incidence.

In summary, estimating the potency of carcinogens in numerical terms is usually not possible because measurements of the level and duration of exposure have not in the past been made and recorded with the required precision and because the precise incidence in exposed and (matched) control groups is seldom available. Nevertheless, the accumulation of observations in humans often allows a rough comparison of the carcinogenic potency of the chemical to be made.

C.1.4. Experimental Data as a Basis for Potency Evaluation

For the majority of chemicals, especially new ones where no human data are available, the estimation of carcinogenic potency in man can be based only on extrapolation from experimental data. The first step in this estimation is the determination of the carcinogenic potency of the chemical in the experimental system. The most appropriate type of experiment from which such a determination can be made is a well designed, adequately conducted animal carcinogenicity study. Key information to be derived from such a study includes:

a) The proportion of animals bearing neoplasms at each exposure level.
   The number of neoplasms per animal.
   The number of different types of neoplasms.
   The number of species affected.
b) The magnitude of the dose at which the carcinogenic response occurs.
c) The organ or target tissue in which the carcinogenic response occurs. It should be recognised that an increase in the number of tumours of a type which occurs spontaneously in a high proportion of the strain of animal being used (e.g. liver tumours or pulmonary adenomas in certain strains of mice) carries less weight in the estimation of potency than does the appearance of tumours in other organs.
d) The latency period before tumour development. The shorter the latency period the more potent is the chemical.
e) The sensitivity of the experimental model.
f) Further information obtained from other toxicological studies such as kinetic and metabolic data. The significance of these in the estimation of potency to man is not clear in every case. Fundamental differences in genetic make-up between animals and man, which can lead to wide variations in response to the action of chemicals, include differences in immune and hormonal status, among others. Only in those situations where it can be demonstrated that the active metabolite (or ultimate carcinogen) and the mechanism of action are the same in an animal and man, and where similarities in exposure conditions, kinetics, metabolic pathways and defence mechanisms have been established, would a quantitative extrapolation of potency have more meaning.

C.1.5. Importance of Metabolism

In assessing the carcinogenic potency of a chemical, the fact that the concentration of the ultimate carcinogen at a specific target site is determined by the administered dose, modified by kinetics and metabolism, should be taken into consideration. Thus, the extrapolation of findings in animal studies to man has to take into account, among other factors, qualitative and quantitative differences in metabolism between test animals and man. There are many examples in which differences in metabolism between different test-animal species and even different strains can be demonstrated.

In addition, the metabolic activity within a given strain of animal may vary considerably with time and with varying experimental conditions, including dose. Such differences may result in large variations in concentration of the active metabolite at the target site.

A further problem exists in the use of data obtained in animal studies at high exposure levels for extrapolating to effects at much lower levels in animals or man. Exposure to high levels may saturate metabolic processes which at low concentrations may rapidly inactivate active metabolites resulting in a lower probability of effective reaction with the target site. Consequently, the dose-response relationship may be quite different after exposure to "high" and "low" levels. Nevertheless, a weak response at high doses generally indicates a low potency.

C.1.6. Importance of Mode of Action

The precise physical, chemical or biological events at the cellular level which induce malignant transformation are not known. There is, however, an association between certain events and the development of malignant neoplasms. The differentiation and division of cells is under the control of the genetic material. Interference with the integrity of DNA and its replication process may lead to the formation of abnormal cells which may develop into a neoplasm if they are outside the normal physiological control of the body. Certain chemical carcinogens have the ability to induce self-replicating errors in the genetic material and it assumed that this is a mechanism by which they induce cancer. Such chemicals are said to have genotoxic carcinogenic activity.

There is now a large body of evidence which supports the view that malignant neoplasms may be produced by chemicals which do not induce self-replicating errors in the genetic material. Such chemicals are said to have non-genotoxic activity. The exact mechanisms of action of such substances are not known, but may well be different from chemical to chemical, reflecting a combination of physical, chemical or biological alterations. Changes in hormone balance and specific enzyme systems, and effects related to immuno-suppression, may be involved in some cases. Other evidence suggests that malignant neoplasms may develop where there is repeated chemical injury to tissue.

The distinction between substances with genotoxic and those with non-genotoxic carcinogenic activity is important because it has a profound bearing on the magnitude of their dose-related carcinogenic activity. It is claimed that for genotoxic carcinogens there is no dose below which carcinogenic activity does not occur. This no-threshold concept is based on the extension to carcinogenicity of the hypothesis that there is, in general, no threshold for mutagenic events. Events due to self-replicating errors in the genetic material could result from the effect of a single molecule in a single cell, and therefore, simplistically, there is no threshold for such an event. This postulate is impossible to prove or disprove experimentally for mutagenic or carcinogenic activity. It ignores the existence of multi-stage processes in carcinogenesis, and of intracellular defense mechanisms and several other supracellular defense mechanisms. Recent evidence suggests that a threshold may exist for the mutagenic activity of chemicals in in vitro systems. Therefore no definitive conclusion can be made about the existence or absence of any threshold for all or some of the substances with carcinogenic activity. Even if a threshold could be established experimentally, the threshold level could not be defined in practice for genetically-heterogenous human populations.

Chemicals with non-genotoxic carcinogenic activity produce a primary toxic event prior to the carcinogenic event. For such chemicals there is no basis for presuming the absence of a threshold. For non-carcinogenic chemicals it is believed, and generally accepted, that a threshold for toxic effects exists. A similar no-effect dose may exist for the primary toxic activity of chemicals with a non-genotoxic carcinogenic activity, and this will be the threshold for their (secondary) carcinogenic activity.

Because of the different response of chemicals with genotoxic and non-genotoxic carcinogenic activity as a function of dose, methods proposed for potency estimation should take into account what is known about the mode of action of each chemical carcinogen.

C.1.7. The Use of Mathematical Models for Predicting Carcinogenic Risk at Low Doses from Long-Term Animal Studies

One unavoidable step in the process of Risk Estimation is the extrapolation from positive results obtained in animal carcinogenicity studies to man (usually exposed to substantially lower doses).

As indicated above, there is no general agreement on the question of whether a dose threshold exists below which no excess of neoplasms would be induced by a chemical with genotoxic carcinogenic activity. Furthermore, thresholds should not be confused with "no observed effect levels", which depend strongly on the resolution of the experimental system used. In the absence of sufficient information to allow the establishment of safety on the basis of the existence of a threshold as normally used in toxicology, the concept of virtual safety has been developed. In this concept, very low dose-levels are assumed to carry a certain minimal risk which is low enough to be acceptable. To obtain an idea of exposure levels associated with such minimal risk, the extrapolation of data from animal experimentation is required. In such experimentation, high dose-levels usually have to be used to produce a measurable incidence of neoplasms in the relatively small number of animals to which, for practical reasons, the experimental groups must be restricted.

In this process of extrapolation, two steps have to be clearly distinguished. The first is the extrapolation of results obtained at high dose-levels in experimental animals to predict incidence at low dose-levels which are experimentally inaccessible. The next step is the extrapolation from this calculated incidence at low dose-levels in animals to the incidence in man at the same dose-levels.

C.1.7.1. Extrapolation from high to low dose-levels

In the first step of extrapolation, models based on mathematical functions of the incidences of neoplasms and dose-levels have sometimes been used. Purely statistical models are based on the assumption that dose-response curves arise from a distribution of individual thresholds within a population. Stochastic models are based on the assumption that a positive response is the result of the random occurrence of a number of biological events, and they therefore have some biological rationale. However, both types of model are based on the assumptions that the metabolic fate of the compound and the reaction of the host are strictly proportional to dose, and both reject the existence of population thresholds, although statistical models assume the existence of a threshold for individuals. Nevertheless, by using these models the expected neoplastic response of the species under investigation to the low-level exposures of interest may then be calculated from the observed incidences at higher doses.

The available mathematical models for the extrapolation from a given set of experimental data may not be appropriate for the following reasons:

1. Despite considerable effort, the mechanisms of chemical carcinogenesis are not completely understood and at present there is insufficient biological

evidence to confirm the appropriateness of any particular model, or evidence that they estimate reliably the incidence at low exposure levels.

2. By the use of suitable mathematical parameters all the models can describe a given set of data points more or less accurately and it is impossible to select the "right" model simply on goodness-of-fit criteria. This is of particular importance because in the low-dose range the cancer incidence calculated using different models and functions, derived from the same experimental results, may differ by several orders of magnitude.

3. The fate of the chemical at the high doses normally administered in animal carcinogenicity studies may be substantially different from the fate of the chemical at low doses because of, for example, saturation of metabolic processes and induction of enzymes involved in the metabolism of the chemical. In addition, reactive defense mechanisms and adaptive responses may not be proportional to dose. Thus the assumption made in all models that, independently of dose levels, the action and fate of the chemical are constant relative to the dose is often not fulfilled in practice.

For extrapolation to the experimentally inaccessible, low-incidence region by currently-available mathematical models an irrevocable prerequisite is the availability of data from a carefully-planned and well-conducted animal study. In addition, the application of mathematical models in Risk Estimation has to be supported by information to clarify the underlying biological processes leading to the observed effect. This may include, for instance, results from short-term tests for carcinogenicity, studies of binding to cellular macromolecules, DNA-repair studies; metabolic and toxico-kinetic data; and information on enzymatic alterations, the proportion of neoplasm-bearing animals, the number of neoplasms per animal, the type and site of neoplasms, and on the aggressiveness of the neoplasm as expressed in its pathogenesis and time-to-occurrence.

Provided that the limitations imposed by the above assumptions and uncertainties are understood, the use of mathematical models may be appropriate as one of the techniques employed by an expert. They can, however, do nothing more than provide a first estimate of the incidence, at low exposure levels, in the animal species and strain under investigation.

C.1.7.2. Extrapolation from animal data to man

The second step, extrapolation from the findings in animals to man at the dose-level of interest, is not amenable to mathematical modelling. This is because in carcinogenic studies with animals the complexity of the human situation, such as the intensity and frequency of exposure, age at first exposure, diet and genetic make-up, and species differences have to be grossly simplified. Extrapolation to man requires the expert judgement of a group with the necessary knowledge and experience to take the results from the first step in extrapolation (including mathematical modelling when appropriate), together with the factors previously discussed, in order to assess the likely qualitative and quantitative response of a human population at the estimated level of exposure. On the rare occasions when adequate epidemiological data are available, a numerical expression of the likely risk is possible. More usually, the data on which the assessment is based are inadequate for numerical expression and it will be possible to express the magnitude only in relative terms i.e. compared with other carcinogens.

At the present state of this art, mathematical models should not be used in isolation for final Risk Estimation. Needless to say, further research on the mechanisms of chemical carcinogenicity is necessary and will certainly result in the development of more versatile models. Critical application of existing models is just one step in this direction.

C.1.8. Categorisation of Carcinogens According to Potency

In the above discussion on the evaluation of potency, some of the many pitfalls present in any attempt to make a simple extrapolation from animal experimental results to human risk have been emphasised. Nevertheless, there is a pressing need to find some acceptable way of categorising carcinogens in terms of their potency so that Risk Estimation and Limitation become possible, and appropriate control measures may be developed. By considering all available data, a categorisation according to potency can be made with reasonable confidence, although in the present state of knowledge chemical carcinogens can be categorised only into the broad classes of high, medium and low potency.

However, because the process of categorisation is neither primarily numerical nor invariable (it will differ from chemical to chemical), it is not possible at present to provide strict rules for it. This is why a group of experienced scientists is required to develop the categorisation for individual chemicals on the basis of expert judgement.

The following are some of the factors from animal and human data which would lead experts to judge that a chemical was of high carcinogenic potency:

- a large increase in the incidence of malignant neoplasms at low exposure levels;
- a large number of malignant neoplasms per individual;
- a short latency period;
- development of malignant neoplasms after a single dose or few doses;
- induction of malignant neoplasms in a variety of organs;
- induction of malignant neoplasms in organs with a low natural incidence of neoplasms;
- induction of a high incidence of malignant neoplasms in a number of strains and species;
- ancillary information on mode of action, metabolism and tissue dose, when available.

Conversely, the following are some of the factors which may lead to categorising a chemical as one of low carcinogenic potency:

- a small increase in the incidence of malignant neoplasms;
- a long latency period;

- the induction of malignant neoplasms only of a type with high and variable natural incidence;

- the induction of malignant neoplasms only at grossly excessive exposure levels;

- the absence of carcinogenic activity in a number of species;

- ancillary information on mode of action, metabolism and tissue dose, when available.

C.2. EVALUATION OF EXPOSURE-RELATED FACTORS

C.2.1. General

Together with the estimation of the potency of the carcinogen, a knowledge of the conditions of exposure are of major importance for Risk Estimation. Exposure to carcinogenic substances implies their presence in the work-place under such conditions that actual or potential contact with individuals is possible. Actual contact may lead to absorption into the body, and this again may or may not lead to the development of cancer in the exposed persons. Whether cases occur depends mainly on the carcinogenic potency of the chemical, the dose and period of exposure, and factors specific to the individual which are, in the main, indeterminable. The purpose of analysing exposure-related factors is to identify the significant sources of exposure, and estimate the exposure quantitatively.

C.2.2. Factors Influencing Exposure

In evaluating individual exposure conditions, the following need to be considered:

a) the intrinsic properties of the substance;
b) factors related to the process;
c) factors related to personnel.

These are detailed in Appendix 2, and only a few of the more general aspects are discussed below.

C.2.2.1. The intrinsic properties of the substance.

Certain intrinsic properties of a substance play a major role in determining whether it will be absorbed systemically. These properties include such biological parameters as bioavailability and metabolism (discussed earlier) which are interrelated with the physical properties and form of the substance. Thus, fine dusts, gases and vapours (and therefore liquids of high vapour pressure) will generally lead to greater atmospheric concentrations at the workplace and greater availability for systemic absorption by inhalation than will pastes, coarse granules, or liquids and solids of low vapour pressure. Liquids and fine dusts are more likely to cause skin contamination by splashing and/or impregnation of clothing, and if the material is also capable of penetrating intact skin the risk is enhanced. Other physical forms, though of less importance, must not be disregarded when considering dermal exposure.

Ingestion of an industrial chemical is unlikely to be an important route of entry, although it should be recognised that dust particles greater than 7 μm in size may be inhaled, trapped in the upper respiratory tract, and carried in the mucus to the pharynx where most of it will be swallowed.

C.2.2.2. Factors related to the process

a) Concentration of the substance in the process. The occurrence of significant exposure depends on whether a susbtance is handled in the process at high concentrations, e.g. as a starting material, a major intermediate, or a final product, or at low concentrations, e.g. as a minor by-product or unstable intermediate. The actual carcinogen may occur as a contaminant or impurity in small concentration in other substances. As this concentration becomes progressively smaller the carcinogenic risk from this contaminated or impure substance will for all practical purposes disappear.

b) Handling conditions. The conditions influencing exposure during handling are more complex to assess, since such widely-varying parameters as plant design, process technology, logistics, working habits and atmospheric conditions must be taken into consideration. For example, poor handling practice can enhance workplace contamination, whereas sophisticated ventilation systems may considerably reduce it. For a thorough evaluation of the total exposure, all of these extrinsic factors must be analysed step by step for every individual technological process, including such ancillary activities as maintenance, transport, storage and disposal.

C.2.2.3. Factors related to personnel

The degree or intensity of contact of individuals with a carcinogen depends on the exposure levels and duration of exposure, both of which may be influenced by the use and effectiveness of personnel protective measures.

With a given exposure level the dose of a carcinogen received will depend mainly on the duration of exposure. For a given plant design and process this duration can be reduced by a number of measures directed at the protection of the exposed individuals. These measures, such as personal protective equipment, good hygiene and training, constitute another set of factors which must be individually considered during the Risk Estimation process.

In this process, the risk to individuals should not be considered to be smaller because only a few people are exposed, and greater if a large number are exposed. In this sense, risk relates to each individual and not to a group.

C.3. OUTCOME OF RISK ESTIMATION

When the Risk Estimation group has assessed the likely potency of the carcinogen to man, it considers the information available on occupational exposure. The group then uses its judgement to decide whether there is likely to be a risk of excesss cancers in the exposed population in a given situation.

For the few Proven Human Carcinogens where there are good historical data on the response at given exposure levels, this judgement can be given reasonably precise limits. However, for other Proven Human Carcinogens, evidence of the likely human response must be based on an assessment of pharmacokinetics, metabolism and mode of action, as well as potency, in animal models. The judgement in this case is therefore less precise and the decision is either that under the given exposure conditions there is likely to be a risk of excess cancers in the exposed population or, alternatively, that this is unlikely.

Thus the end-result of Risk Estimation is an expert judgement of risk which is vital for the deliberations of the Risk Limitation group. It is one of the tasks of this latter group to judge what level of risk, and therefore exposure, is acceptable or reasonable.

D. RISK LIMITATION

In this final stage of risk assessment, information from the Risk Estimation stage is considered in the context of many other necessary factors, for example:

- the social and economic advantages and penalties;
- the technological feasibility and the cost of implementing the recommended control measures;
- the availability of analytical and monitoring methods to measure exposure;
- the existence of alternative chemicals or processes.

The end-result of this stage is the development of recommendations governing exposure conditions, the handling of the carcinogen, and any other measures necessary to ensure that the risk is controlled to a suitably low level by means which are technologically feasible and take into account the social and economic consequences of the proposals. It is of course important that the recommended level of exposure is measurable in practice, i.e. that adequate analytical and monitoring techniques are available. The recommendations may include the specification of atmospheric exposure levels for gases, vapours and dusts, and of industrial hygiene measures (including working conditions) for non-volatile liquids or solids where the main contact is other than by inhalation.

Risk Limitation should be considered by a group in which are represented the parties ultimately concerned with implementing the recommendations made to control the risk, plus experts from the Risk Estimation group. Such a group will sometimes operate within a legislative process.

As new information becomes available, a re-evaluation should be carried out in order to improve the overall risk assessment. Uncertainties in risk assessment should not lead to deliberate over- or under-estimation of risk, as either could act against the best interests of the groups most closely concerned.

When recommendations from the Risk Limitation group become available, measurements of the actual exposure or an assessment of the exposure conditions should be compared with those specified in the recommendations and, where necessary, technical or organisational changes should be made to achieve compliance with them. Generally, technological measures such as changes in the chemistry of the process or changes to the plant or ancillary equipment are most effective in reducing risk. When containment of the carcinogen cannot be achieved immediately by such measures, improvements in personal protection, or other organisational measures, should be implemented but should generally be regarded as temporary. Reference back to the assessment of exposure-related factors in the Risk Estimation stage will provide important indications of the major sources of exposure, and hence of areas where effort may be most effective in reducing risk.

As far as is reasonably practicable, the number of people exposed to occupational carcinogens should be minimised by appropriate technological and organisational measures.

In the description of risk assessment given in this Monograph the need to take into account the possibility of exposure due to accidents has not so far been mentioned. However, it is very important that for Proven and Putative Human Chemical Carcinogens of high potency, adequate and rapid measures should be planned to detect and deal with such accidental exposure.

Only a few general remarks concerning protective measures have been made in this document because, strictly speaking, the organisation of cancer prevention at the workplace and the medical surveillance of exposed workers are not a part of risk assessment. However, risk assessment plays a decisive role in setting priorities for prevention and surveillance.

APPENDIX 1

CONCLUSIONS BASED ON SHORT-TERM TESTS FOR CARCINOGENICITY

Most toxicological information is quantitative, and the majority of the information in, for example, the EEC toxicological base-set is no exception. Thus, for example, the reporting of acute oral or dermal toxicity is given as an LD50 expressed as a numerical value of dose per unit body weight. One notable exception to this rule is short-term testing for mutagenicity or carcinogenicity. There are in fact very good scientific reasons, e.g. quantitative and qualitative differences in metabolism, for not using data from short-term tests for a numerical quantification of mutagenic and/or carcinogenic risk in man. Such data are relavent to assessing carcinogenic potential.

The consequence is that the qualitative nature of the result (either positive or negative) puts particular emphasis on its accuracy. It is not possible to calculate the probability of error of a result expressed only as "positive" or "negative". This emphasises the need for a high degree of certainty that the qualitative result is correct, so that subsequent decisions are made on a sound footing.

In considering what decisions should be taken on the basis of a positive or a negative short-term test, the first and most important step is to establish that the result is "confirmed". There are several conditions which must be met before a result can be considered confirmed, and one of the most important is that the result from a second short-term test should be in agreement (see below). Carcinogenic or non-carcinogenic activity is suggested only when this and other conditions are met.

Special problems, which are not yet resolved, are presented by mixtures, and thus results from the testing of mixtures should be regarded with caution.

1. Requirements for a "confirmed" result.
For the result of testing a chemical in short-term tests to be considered "confirmed", it must meet the following criteria:

1.1. The result should be derived from a test carried out to a protocol meeting minimum criteria (i.e. the protocol should be supported by a formal validation study) or the "chemical class control pairs" should have performed as expected in the same experiment. (A "chemical class control pair" is defined as a pair of chemicals, both structurally-related to the chemical under test, one of which is carcinogenic and the other non-carcinogenic.)

1.2. The result should be the same in two test systems with unrelated end-points.

1.3. The result should be consistent with the experimental design, e.g. there should be a clear dose-response relationship; where no increase in colonies is seen in a bacterial mutation test, it should be established that this is not due to high toxicity; in a bacterial mutation test, an increase in colony counts should be confirmed by replicate plating.

1.4. The positive controls used to check the reliability of the test should be used in parallel with each experiment.

1.5. The result should be reproducible if performed at different times in separate laboratories.

1.6 An assessment should be made of the likely contribution of impurities to the test result. Impurities which are strongly positive in the test system or highly toxic to the test organism can lead to incorrect results.

2. An unconfirmed result
If any one of the above criteria is not met, the result becomes an unconfirmed result.

3. Consequences of a confirmed positive result
Since there are sufficient controls and checks in the experiments leading to a confirmed result, it has certain characteristics, namely: it is reproducible; it is consistent with the known response of the tests to that chemical class; each test is shown to have been performing accurately at the time of the experiment; the chemical itself is responsible for the result; and the result is the same in two tests. These controls and checks provide a result which is the best possible indication of carcinogenicity short of actually carrying out an animal carcinogenicity study, although it falls short of proof of carcinogenicity. If any one of the criteria for regarding a result as confirmed is not met, it should be considered an unconfirmed result.

4. Consequences of a confirmed negative result.
In the absence of other relevant toxicological data, a confirmed negative result from short-term tests is a good indication of non-carcinogenicity.

However, other considerations, e.g. the size of the exposed population and the likely dose absorbed, may make it prudent to carry out additional testing in whole animal systems.

5. Consequences of an unconfirmed result

There are many occasions when the result is unconfirmed e.g. if it is positive in only one test, or if the results are not fully reproducible. An unconfirmed result is a temporary situation and generally needs further studies in order to confirm the positive result or to obtain a confirmed negative result. If the result remains unconfirmed, then expert judgement regarding the significance of the unconfirmed result is required when it is used, with all the other factors available, as one element in the process of risk assessment. Whatever decision is taken, it should be reviewed when new information becomes available and the result becomes confirmed.

The data produced by short-term tests can be considered as part of the process of identifying carcinogenic potential. Other points (including chemical and toxicological properties and exposure conditions), have to be taken into account for risk assessment and, thus, the decisions taken must be based on a consideration of all the data for each chemical and situation.

APPENDIX 2

DETAILS OF FACTORS INFLUENCING EXPOSURE

1. Factors Related to Intrinsic Properties of the Material

1.1. Physical and chemical properties and physical form:

- gas
- liquid (boiling-point, vapour pressure)
- solid (wet or dry, particle size)
- solubility
- reactivity (possibility of neutralisation, etc)
- ease of removal (in case of spill, escape)

1.2 Toxicological properties which themselves lead to a limitation of exposure, for example irritancy, corrosivity, etc.

1.3. Detectability

- odour
- availability of analytical methods for determining exposure level
- availability of analytical methods for detection in effluents, exhaust air, reaction mixtures, residues, etc
- availability of monitoring methods

2. Factors Related to the Process

2.1. Status of material under consideration in the process:

- starting material (reactant)
- major intermediate (isolated/not isolated)
- minor or unstable intermediate
- desired product
- impurity

- solvent or other auxiliary substance

2.2. Type of process:

- batch
- continuous

2.3. Size of process:

- gross material turnover per year
- batch size
- number of batches per year

2.4. Processing system:

- open/closed equipment
- open-air or enclosed plant

2.5. Sources of workplace contamination (exposure) in the processing system:

- charging of materials
- ventilation (filters, washers, cyclones, etc)
- effluents
- leaks (especially gases and liquids)
- spillage (especially dusts, and splashing of liquids)
- maintenance and repair operations
- going on- and off-stream

2.6. Sources of workplace contamination (exposure) in ancillary systems:

2.6.1. Transport
- bulk material (especially liquids and gases)
- packed material
- loss of containment due to road or rail accidents
- loss of containment due to breakage or perforation of individual containers
- effect of small leaks (especially from punctured bags or leaking flanges)
- means of decontamination and cleaning of vehicles and spilling areas

2.6.2. Storage
- above, at or below atmospheric pressure
- warehouse or open-air storage
- suitability of storage area (ventilation, size, height, possibility of cross-contamination, etc)
- fire and explosion hazards
- handling during storage (loading, unloading, repacking, etc.)

2.6.3. Disposal
- residues from technological processes to be considered with respect to quantity, frequency and physical form (liquids, solids, tars, etc)

- other materials to be disposed of e.g. packaging materials, cleaning materials, disposable protective equipment, equipment to be scrapped
- way of disposal, e.g. burning (type, suitability and location of incinerator); depositing (controlled/uncontrolled, bulk/packed, above-ground/underground, geological and atmospheric conditions, etc); others (regeneration, recycling, shredding, etc).

3. Factors Related to Personnel

3.1. Personal protective equipment (to be assessed for suitability, duration of use, cleaning methods, etc):

- protective clothing (full or partial protection)
- goggles/face shields
- respirators/gas masks
- separate air supply

3.2. Hygiene measures:

- availability of working overalls and underwear (number; disposable or to be washed)
- cleaning of clothes (who, where)
- frequency and obligation of changes
- availability and use showers/baths
- type and suitability of cloak-rooms
- eating, drinking, smoking in working-area
- ease, frequency and methods of cleaning working area
- possibilities of spreading contaminating material outside working area (by persons)
- protection of outsiders coming into working area (restricted areas)

3.3. Training, instruction:

- extent, adequacy
- effect, identification
- adherence

APPENDIX 3

TASK FORCE CARCINOGENICITY

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APPENDIX 4

ECETOC MONOGRAPHS, TECHNICAL REPORTS AND DOCUMENTS

TITLE	REFERENCE	DATE
"Draft for Ecological Hazard Evaluation", for 6th Amendment.	ECETOC Doc-1	19.06.79
"Comments to EPA on Proposed GLP Standards for Health Effects".	ECETOC Doc-2	20.08.79
"Comments to EPA on Proposed Health Effects Test Standards for TSCA Test Rules".	ECETOC Doc-3	03.10.79
"Good Laboratory Practice"	Monograph N° 1	Oct. 1979
"Comments to FDA on Non-Clinical Laboratory Studies", Amendment of GLP Regulations.	ECETOC Doc-4	28.12.79
ECETOC Brochure	—	May 1980
"Definition of Teratogen" for 6th Amendment.	ECETOC Doc-5	24.06.80
"Contribution to Strategy for Identification and Control of Occupational Carcinogens".	Monograph N° 2	Sept. 1980
"Definition of a Mutagen", for 6th Amendment.	See Appendix in Monograph N° 2	Sept. 1980
"Relevance of Model Experiments to Photodegradation in the Environment".	ECETOC Doc-6	01.10.80
"Biodegradation Methodology", in 6th Amendment.	ECETOC Doc-7	28.10.80

"Abiotic Degradation Testing", in 6th Amendment.	ECETOC Doc-8	28.10.80
"Test Method for Acute Toxicity to Daphnia Magna", for 6th Amendment.	ECETOC Doc-9	28.10.80
"Skin Sensitisation", test methods etc.	ECETOC Doc-10	29.10.80
"Prolonged Toxicity Study with Daphnia Magna".	ECETOC Doc-11	24.11.80
"Criteria for Choosing Chemicals for Testing".	ECETOC Doc-12	19.12.80
"Organisation of Jointly-sponsored Studies".	ECETOC Doc-13	20.12.80
"ECETOC Statement on Formaldehyde".	ECETOC Doc-14	16.02.81
"Summary of Results Presented at the CIIT Conference on Formaldehyde Toxicity on 20-21st November 1980".	ECETOC Doc-15	27.02.81
"Assessment of Data on the Effects of Formaldehyde on Humans".	Technical Report N° 1	13.05.81
"The Mutagenic and Carcinogenic Potential of Formaldehyde".	Technical Report N° 2	18.05.81
"Assessment of Test Methods for Photodegradation of Chemicals in the Environment".	Technical Report N° 3	03.08.81
ECETOC Colloquium Photodegradation	ECETOC Doc-16	14.10.81
ECETOC Brochure, 2nd edition	—	Dec. 1981

1. CARCINOGENIC MATERIALS

1.1 Field of Application

List of carcinogenic materials

Points 1.1 to 1.5 are valid for the carcinogenic materials listed below:

Carcinogenic Material	Groups			IV Existing EEC Classication
	I (Very severely hazardous)	II (Severely hazardous)	III (Hazardous)	
	% w/w in the material			
N-Dimethyl nitrosamine	≥0.01	<0.01–0.001	<0.001–0.0001	
Dimethyl carbonic acid chloride	≥0.05	<0.05–0.005	<0.005–0.0005	
Hexa methyl phosphoric acid triamide	≥0.05	<0.05–0.005	<0.005–0.0005	
Sym. Dichloro dimethyl ether	≥0.05	<0.05–0.005	<0.005–0.0005	T, R39
4-Amino diphenyl	≥1	<1 –0.1	<0.1 –0.01	
Benzidine and its salts	≥1	<1 –0.1	<0.1 –0.01	T, R39
Mono chloro dimethyl ether[1]	≥1	<1 –0.1	<0.1 –0.01	
2-Naphthylamine	≥1	<1 –0.1	<0.1 –0.01	T, R39
Propansultone	≥1	<1 –0.1	<0.1 –0.01	
N-Chloro formyl morpholine		≥0.005	<0.005–0.0005	
Acrylonitrile		≥1	<1 –0.1	T, —
Asbestos[2]		≥1	<1 –0.1	
Benzene		≥1		T, R39
Beryllium and its compounds[2]		≥1	<1 –0.1	T, R39
Calcium chromate[2]		≥1	<1 –0.1	
Chromium (III) chromate[2] (chromic chromate)		≥1	<1 –0.1	
Diethyl sulphate		≥1	<1 –0.1	T, —
Diazo methane		≥1	<1 –0.1	
1.2-Dibromo xethane		≥1	<1 –0.1	T, —
1.2-Dibromo-3-chloropropane		≥1	<1 –0.1	T, —
3.3′-Dichloro benzidine		≥1	<1 –0.1	
Dimethyl sulphate		≥1	<1 –0.1	T, R40
Ethylenimine		≥1	<1 –0.1	T, R40
Iodomethane (Methyl iodide)		≥1	<1 –0.1	T, —
Cobalt [2,3] (in the form of inhalable dusts of metallic cobalt and only slightly soluble cobalt salts)		≥1	<1 –0.1	
4.4-Methylene-di (2-chloraniline)		≥1	<1 –0.1	
Nickel carbonyl		≥1	<1 –0.1	T, R40
5-Nitro acenaphthene		≥1	<1 –0.1	
2-Nitro naphthaline		≥1	<1 –0.1	
2-Nitro propane		≥1	<1 –0.1	T, —
B-Propiolactone		≥1	<1 –0.1	

[1] The classification relates to the technical monochloro dimethyl ether, which, according to experience to hand, can contain up to 7% of dichloro dimethyl ether as an impurity.

[2] If the material can occur in an inhalable form (with asbestos, as a fine powder) whilst being handled.

Carcinogenic Material	Groups I (Very severely hazardous)	 II (Severely hazardous)	 III (Hazardous)	IV Existing EEC classification
	% w/w in the material			
Propylene imine		≥1	<1 -0.1	
Strontium chromate [2]		≥1	<1 -0.1	
Vinyl chloride		≥1	<1 -0.1	T, R39
Zinc chromate[2]		≥1	<1 -0.1	
Arsenic trioxide and pentoxide, arsenious acid, arsenic acid and their salts[2]		≥3	<3 -0.3	T, —
Nickle[2,3] (in the form of the inhalable dusts of metallic nickel, nickel sulphide and sulphidic ores, nickel oxide and nickel carbonate) as well as nickel compounds in the form of inhalable droplets.		≥5	<5 -0.5	
1-Chloro-2.3-epoxy propane (Epichlorhydrin)			≥1	T, —
1.1-Dimethyl hydrazine			≥5	
Hydrazine			≥5	T, R40
Pitch[2] Tars			≥5	
Tar oils in bitumen			≥5	

[2] If the material can occur in an inhalable form (with asbestos, as a fine powder) whilst being handled.
[3] This does not include alloys.

1.1.2. Carcinogenic materials which do not attain the lower percentages by weight given for Group III in the list under 1.1.1.

If the employer is manufacturing or using carcinogenic materials which do not attain the lower percentages by weight given for Group III in the list under Number 1.1.1. and with which, according to past experience, the Technical Guidance Concentration can be exceeded, Numbers 1.3 to 1.5 are correspondingly valid for materials in Group III.

1.2 Obligation to Ascertain

The employer who is dealing with a material, must, in any doubtful cases, ascertain whether he is dealing with a carcinogenic material. The employer can work from the assumption that a label is applicable, to be found on the packaging or on attached paperwork.

1.3 Notifications and Restrictions

(1) If the employer:

1. manufactures a carcinogenic substance from Group I or II or uses it in a manufacturing process during which such a substance occurs,
2. uses a carcinogenic material from Group I or II for the purposes of manufacturing a material,

then he must report this without delay to the responsible authorities. Described in the report must be

- the characteristics of the carcinogenic material,
- the manufacturing process,
- the protective measures,
- the number of employees who can be exposed to the effects of the carcinogenic material.

(2.) If the employer is using a carcinogenic material from Group I in order to manufacture a material with it, then he must demonstrate to the authorities responsible that the substance, the preparation or any other product manufactured with the characteristics identifying them cannot be manufactured with any other non- or less-hazardous material. The authorities responsible can prohibit the employer from using the carcinogenic material, if a non- or less-hazardous material is available.

(3.) If the employer is using a carcinogenic material from Group II in order to manufacture a material with it, then he must demonstrate to the authorities responsible on demand that the substance, the preparation or any other product manufactured with the characteristics identifying them cannot be manufactured with any other non- or less-hazardous material. The authorities responsible can prohibit the employer from using the material, if another non- or less-hazardous material is available and if no disproportionate hardship would arise.

(4.) If an employer is using a carcinogenic material for the purpose of producing a production capacity, then he must demonstrate to the authorities responsible, in every case with substances from Group I and with substances from Group II upon demand, that the production capacity cannot be achieved with any material that is non- or less-hazardous. The authorities responsible can prohibit the employer from using the carcinogenic material if another non- or less-hazardous material is available and — with carcinogenic materials from Group III — if no disproportionate hardship would arise.

(5.) Paragraph 4 is not valid for the employers who are using the carcinogenic materials for the purpose of producing production capacities if they are using the materials employing officially or trade association-recognized processes or equipment. Neither are paragraphs 3 and 4 valid if carcinogenic materials

1. are being manufactured or used for research purposes,

2. are being used for the purpose of testing their properties or their composition, or,

3. are being used as reference substances for analytical tests.

(6) In so far as dealing with certain carcinogenic materials is prohibited by this regulation or in the accident prevention regulations of a person covered by legal accident insurance, these requirements remain unaffected.

1.4 Precautionary Measures

1.4.1 Technical Safety Measures

1.4.1.1 Principle

The employer must take care that the concentration of carcinogenic substances in the air at the workplace which is unavoidable according to the state of the art is restricted to a minimum. If a working procedure is introduced for the first time then the technical safety measures must be complied with, using the given state of technology at the time. If the safety technology of the working procedure has been further developed, if this proves considerably good or considerably increases the degree of safety at work, then the employer must adapt any working procedure which is not corresponding to this further development so that it complies with this further development within a given period.

1.4.1.2 Sequence

1. The working procedures must basically be designed in such a way that no gases, vapours, mist or dust are released whilst dealing with carcinogenic materials. If this is not possible for operational reasons, care must be taken that the gases, vapours, mist or dust are extracted off at the point at which they emerge or arise and that they are removed harmlessly. If extraction is not possible for operational reasons, care must be taken by means of other technical ventilation measures for gasses, vapours, mist and dust as far as possible not to emerge or for the admissible concentration of the material in the air at the workplace not to be exceeded. The employer must make available suitable personal protective equipment if the employees are being exposed to the effects of gases, vapours, mists or dusts in the workplace air.

2. If solid or liquid carcinogenic materials are being handled, the works waste-pipe must be designed in such a way that, as far as possible, the employees are not exposed to the effects of these materials.

1.4.1.3 Measurements

At given time intervals, the employer must measure the concentration of the carcinogenic material in the workplace air, if it has to be reckoned with that the employees are being exposed to the effects of this material. The readings must be recorded.

1.4.2 Hygienic Measures

1. Working clothes and personal protective equipment including protective clothing must be kept separately if they are contaminated by carcinogenic materials. Working clothes and protective clothing must be cleaned by the employer and, if necessary, destroyed. If working clothes have to be destroyed, then the employer must make available the means for new working clothes; destroyed working clothes must be replaced in accordance with the last sentence of Number 1.4.1.2, Paragraph 1.

2. Employees who are exposed to the effects of carcinogenic materials may not eat, drink or smoke in workrooms.

3. Separate washrooms and washing facilities must be made available to employees who are exposed to the effects of carcinogenic materials, if other employees would otherwise be endangered.

1.4.3 Industrial Medical Precautionary Examinations

If it has to be reckoned with that an employee is being exposed to the effects of carcinogenic materials, then the employer may only employ him and, after a period of 5 years, may only further employ him, if he is examined by an authorized doctor.

1.4.4 Restrictions on Employment

1. Employees may not be exposed to the effects of carcinogenic materials from Group I. Sentence 1 is not valid

- for jobs which are compulsorily necessary to dispose of "incidents" in the works or damage and the supervisory measures necessary for this, if personal protective equipment is used; the employee may not be constantly engaged in this work,
- in so far as the carcinogenic material is being manufactured or used in a laboratory for research purposes or for testing its composition or properties,
- in so far as carcinogenic materials are being used as reference substances for analytical tests.

2. If employees are engaged in dealing with carcinogenic materials from Group II, and if it is established by a measurement in accordance with Number 1.4.1.3 that the workplace concentration named in sentence 1 of Number 1.4.1.1 has been exceeded, then the employer must report this straight away to the employees concerned and directly take suitable measures in order to reduce to the named concentration. If the workplace concentration named in sentence 1 of Number 1.4.1.1 is not reached after a given period, the employee can refuse to be employed at his place of work.

3. If an employee, in dealing with carcinogenic materials, is exposed to the effects of these substances, then he may not be engaged in activities which lead to an increase in cancer risk to him by reason of their dependence on rate of work, especially through stronger inhalation or absorption through the skin.

1.4.5 Time Limits

If employees are engaged in dealing with carcinogenic materials, then they may not be exposed to the effects of the carcinogenic materials in this longer than 8 hours/day or longer than 40 hours/week — with plants working 4 shifts per day, 42 hours per week on average over four consecutive weeks.

1.4.6 Use of Recognized Procedures and Equipment

The obligation to measure and record in accordance with Number

1.4.1.3, the working restriction in accordance with Number 1.4.4 Paragraph 3 and the time limit in accordance with Number 1.4.5 are not valid if the materials are being used employing officially or trade association-recognized procedures or equipment.

1.5 Supplementary Regulations for Specific Carcinogenic Materials

1.5.1 Arsenic

1.5.1.1 Application Ban
Materials which contain more than 0.3% w/w of arsenic may not be used

1. for cleaning in transportable containers and other small spaces,
2. in dyes and paints,
3. in plant protection products and pesticides (e.g. seed dressings),
4. in the manufacture of sheet glass (window glass) and glass packaging for foodstuffs,
5. in the production of leather, in the preparation of tobacco products, in textile finishing and in animal preparations,
6. in the manufacture of enamel,
7. in disinfectants and cleaning agents, with the exception of phosphoric acid mordants,
8. in the chemical (reductive) metal deposition for the treatment of surfaces,
9. in the manufacture of pyrotechnical articles,
10. in metal adhesives,
11. as a preservative, with the exception of wood preservatives for outside use (e.g. railway posts).

1.5.1.2 Industrial Medical Precautionary Examinations
If it has to be reckoned with that an employee is being exposed to the effects of materials containing arsenic, then the employer may

1. only employ him,
2. only further employ him after a period of 6 months since the first precautionary examination,
3. during the subsequent period, only further employ him after a period of 12 months since the last precautionary examination,

if he has been examined by a doctor within the time limit in accordance with sentence 1 of §17, Paragraph 2.

1.5.2 Benzene

1.5.2.1 Application Ban
Materials which contain more than 1% w/w of benzene may not be used

1. as a cleaning or degreasing agent (e.g. for surfaces, apparatus, work equipment, other articles),
2. as a solvent or diluent for paints, polishes, corrosives, impregnating agents, caulking, insulating agents, cement, filler, floor or shoe polish, adhesives, rubber solutions, building preservatives, coating agents, mastic, paint removers.

1.5.2.2 Industrial Medical Precautionary Examinations

If it has to be reckoned with that an employee is being exposed to the effects of materials containing benzene, then the employer may

1. only employ him,
2. only further employ him after a period of 2 months since the first precautionary examination,
3. only further employ him after a period of 6 months since the last precautionary examination,

if he has been examined by a doctor within the time limit in accordance with sentence 1 of §17, Paragraph 2. In cases under sentence 1 Number 3 the subsequent examinations must be undertaken within a period of 3 months before the time limit expires.

1.5.3 Vinyl Chloride

1.5.3.1 Long-Term Limit Value

The employer must take care that the admissible concentration of the substance in the workplace air, at least a concentration of 3 ppm vinyl chloride, is not exceeded.

1.5.3.2 Measuring Standards

When taking the measurements, in accordance with Number 1.4.1.3, the employer must apply the measuring standards drawn up by the Hazardous Materials Board, in which the measuring standards of Council Directive No. 78/610/EEC dated 29th June 1978 for the harmonization of the laws and administrative provisions of the Member States for the protection of the health of employees who are exposed to vinyl chloride monomer, (ABl. EEC No. L197 P. 12) are adopted in their respective versions and have been published in the Federal Work Sheet by the Federal Minister for Employment and Social Affairs.

1.5.3.3 Protective Measures

1. In order to recognize normal increases in the vinyl chloride monomer concentration, a monitor system must be arranged at the place where such increases can occur, with which these increases can be ascertained. In the case of an increase in concentration of this type, technical precautions must be taken straight away by which the cause of the concentration increase can be determined and can be eliminated.
2. The level representing the alarm threshold at any measuring point may not exceed an average over one hour above 15 ppm or an average over 20 minutes above 20 ppm or an average over 2 minutes above 30 ppm. If the alarm threshold value is exceeded individual protective measures must be taken without delay.
3. In certain jobs (e.g. cleaning autoclaves, maintenance and repairs) during which technical processing and ventilation measures cannot ensure that the concentration remains below the limit value, suitable individual protective measures must be provided.

1.5.3.4 Industrial Medical Precautionary Examinations

If it has to be reckoned with that an employee is being exposed to the effects of vinyl chloride monomer, then the employer may

1. only employ him,
2. only further employ him after a period of 12 months since the first precautionary examination,
3. during the subsequent time, only further employ him after a period of 24 months since the last precautionary examination,

if he has been examined by a doctor within the time limit in accordance with sentence 1 of §17, Paragraph 2. In cases under sentence 1 No. 2, the subsequent examinations must be undertaken within a period of 6 months before the time limit expires.

1.5.4 Acrylonitrile

1.5.4.1 Industrial Medical Precautionary Examinations

If it has to be reckoned with that an employee is being exposed to the effects of acrylonitrile, then the employer may

1. only employ him,
2. only further employ him after a period of 2 years since the last precautionary examination,

if he has been examined by a doctor within the time limit in accordance with sentence 1 of §17, Paragraph 2. In cases under Sentence 1 No. 2, the subsequent examinations must be undertaken within a period of 1 year before the time limit expires.

1.5.5 Asbestos

1.5.5.1 Industrial Medical Precautionary Examinations

If it has to be reckoned with that an employee is being exposed to the effects of fine dust containing asbestos, then the employer may

1. only employ him,
2. only further employ him after a period of 3 years since the last precautionary examination,

if he has been examined by a doctor within the time limit in accordance with (1) Paragraph 2, sentence 1. In cases under Sentence 1 No. 2, the subsequent examinations must be undertaken within a period of 2 years before the time limit expires.

1.5.6 Calcium Chromate, Chromium (II) Chromate, Strontium Chromate, Zinc Chromate

1.5.6.1 Industrial Medical Precautionary Examinations

If it has to be reckoned with that an employee is being exposed to the effects of calcium chromate, chromium (III) chromate, strontium chromate or zinc chromate, then the employer may

1. only employ him,
2. only further employ him after a period of 9 months since the first precautionary examination,
3. only further employ him after a period of 24 months since the last precautionary examination,

if he has been examined by a doctor within the time limit in accordance with sentence 1 of §17, Paragraph 2. In cases under Sentence 1 No. 2 the subsequent examinations must be undertaken within a period of 3 months before the time limit expires. In cases under Sentence 1, No. 3 the subsequent examinations must be undertaken within a period of 1 year before the time limit expires.

1.5.7 Pitch, Tars and Tar Oils in Bitumen

1.5.7.1 Industrial Medical Precautionary Examinations

If it has to be reckoned with that an employee is being exposed to the effects of pitches, tars or tar oils in bitumen, then the employer may

1. only employ him,
2. only further employ him after a period of 3 years since the last precautionary examination,

if he has been examined by a doctor within the time limit in accordance with Sentence 1 of §17, Paragraph 2. In cases under Sentence 1 No. 2, the subsequent examinations must be undertaken within a period of 1 year before the time limit expires.

Monograph no. 3
January, 1982

C·I·L Inc.

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October 18, 1982

Dr. J.F. Mustard
Advisory Council on Occupational
Health & Occupational Safety
400 University Avenue
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

Re: The Control of Workplace Carcinogens

We have reviewed the documents, "The Control of Workplace Carcinogens" and the "Background Report of the Special Advisory Committee on Carcinogens". However we have confined our comments to the discussion paper because while it sets out to present some of the major issues to be considered in a carcinogen policy, it actually describes a means to regulate both proven carcinogens and unproven but suspect carcinogens in the workplace. Since the proposal has major international implications we circulated it to toxicologists from our affiliated companies, ICI (U.K.) and ICI Americas, and their advice and concern has been taken into consideration in preparing our response.

We found the points presented in the document to be somewhat inconsistent with each other and the recommendations to be inadequately justified. Our most serious concerns are:

1) The absence of any attempt to place occupational cancer in perspective with other causes of death and disability in the workplace;

2) The degree of reliance placed on in-vitro and animal testing as predictors of human carcinogenesis;

3) The underestimation of the impact of the advocated approach to carcinogen control.

We consider that the report's recommendations are largely impracticable and that they will neither protect the health of workers nor allow for the maintenance of a competitive chemical industry in Ontario. Furthermore, we are very concerned that the limited research and health professional resources available for Occupational Health in Ontario could be diverted away from efforts that we know will maintain and improve the health of workers, to ones of questionable efficacy.

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C·I·L House 90 Sheppard Avenue East Willowdale, Ont.

In the report the Advisory Council raises a number of issues regarding the implementation of a cancer policy for Ontario but neglects to address other more fundamental issues. For example, neither the significance of chemical carcinogenesis as a cause of death and disease in the workplace, nor the need for a unique cancer policy in addition to the existing mechanisms for controlling all chemical hazards in the workplace, are explored in any depth.

Recent studies by Doll and Peto(1) suggest that while 75% of all cancers may be directly linked to lifestyle (tobacco, alcohol, diet and sexual behaviour) only 2-8% with a best estimate of 4% are attributable to occupation. While we accept that widespread societal concern with cancer may make it politically expedient to regulate suspected carcinogens in the workplace, we remain unconvinced that focussing attention and resources on health risks that are in many instances scientifically unsubstantiated, is in the best interest of workers.

The report justifies the singling out of new carcinogens for special regulatory treatment on the basis that cancer can be prevented by controlling exposure and that such control is feasible. Firstly, the argument of exposure control to reduce disease in the workplace can be equally applied to all occupational diseases. Secondly, we believe that the effectiveness of the ALARA principle as a means of achieving control will be progressively weakened as the number of chemicals to which it is applied is increased. The Occupational Health and Safety Act and Bill 110 already provide an effective mechanism for the reducing of the likelihood that "bad actors", including human carcinogens, will enter regular commercial use, and we do not think that there is merit in a unique approach to the control of each class of chemical hazard.

We have great difficulty with the expressed opinion that present scientific knowledge allows us to predict, through structural correlations and animal testing, those chemicals which will have real carcinogenic potential in man. Scientific uncertainties associated with this approach are not developed in the report.

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(1) Doll, R. and Peto, R., "The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the U.S. Today", Journal of the NCI, 66 (6), 1191-1308 (1981).

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We were suprised to see the recommendation that both chemical structure and tissue accumulation should be used in assessing the potential carcinogenicity of chemicals. Knowledge of the structural correlates of carcinogens is still very limited and in a comprehensive symposium(3) on this subject the consensus was that while the technique may be useful in the future, much more research into the comparative metabolism and pharmokinetics of chemicals within a general group is necessary. In addition, we would be particularly interested to know why tissue accumulation per se should be equated with suspicion of carcinogenic potential.

A regulatory approach that would be unique to Ontario has been proposed by Council. However, any policy having such a far reaching impact on the economy should be compatible with international standards, unless it can be unequivocally demonstrated that international standards are inapprorpiate. No justification for an Ontario-specific standard has been presented in this report and the adverse effects of such incompatibility on the chemical industry are not addressed.

Similarly, no justification is given for the proposed classification system for carcinogens even though it does not follow any existing established and accepted system. It bears some resemblance to the approach proposed in the original and now outmoded OSHA generic policy. Council should be aware that this policy is under active review by OSHA at present and it is believed that the entire policy will revert to a case by case regulatory approach using guidelines on regulation now being prepared by an inter-agency group. The classification scheme proposed in the report, while it may be bureaucratically attractive, will almost certainly be difficult to administer in practice. The Council may also be aware of the ECETOC monograph(2) outlining the European Chemical Industry's views regarding classification which is based to a large extent on the IARC System and expertise. The OECD Step Sequence Group in Europe carefully studied sequential testing procedures for the classification of carcinogens but finally recommended against the adoption of any automatic testing sequence.

We question the rationale for treating existing chemicals to be used in a new plant (which will generally be built to higher standards) as new chemicals? This will surely be a disincentive to innovation and modernization in the Ontarian Chemical Industry.

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(2) ECETOC Monographs, Risk Assessment of Occupational Chemical Carcinogens, 1982.

(3) An FDA Symposium on Structural Correlates of Carcinogensis and Mutagenesis — A Guide to Testing Priorities (1977).

.../4

The magnitude of the task of effecting Council's proposal for the testing of chemicals that are "not considered new" would be enormous. The TOSCA inventory consists of some 58,000 chemicals and our company alone manufactures and distributes over 7,000 substances. To suggest that all the substances on the EPA list should be properly categorized within five years following the protocol suggested in the report is nothing short of ludicrous. The facilities do not exist in Ontario or elsewhere in the world for testing on this scale and the cost for a two species bioassay (required if in vitro tests are either questionable or positive) exceeds $1 million per compound! Without wishing to appear facetious, we find ourselves wondering if this is not an attempt to create long-term business for the proposed Joint Centre for Toxicology!

In conclusion, we would strongly urge the Minister to reject the recommendations of this discussion document as being detrimental to the goals of protecting worker health and maintaining the viability of the chemical industry in this province.

We would suggest that the present legislative framework, including the designated substances program which already regulates some known human carcinogens and which could be expanded to include others, provides a suitable mechanism for controlling workplace carcinogens. If the Minister deems it necessary to introduce a separate carcinogen policy this should only be developed following a much more extensive and scientifically reasoned review than is provided by the present discussion document.

Yours truly,

Elizabeth Kaegi

Elizabeth Kaegi, M.B.Ch.B., M.Sc.
Medical Director

Peter G. Nicoll

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Dr J F Mustard
Chairman
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400 University Avenue
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Dear Dr Mustard

I have recently reviewed the discussion paper on "The control of Workplace Carcinogens" and I understand that the council is inviting comments and suggestions on this subject.

The paper offered some very valuable suggestions on the topic, and provides a good framework for future policy direction. There are two points I would like to add to the discussion:

1. With regard to the identification and classification of chemicals (p12), the discussion has suggested that categories I, II and III should respectively designate chemicals as carcinogens, chemicals of uncertain status and non-carcinogens.

I would like to suggest a fourth category, which in the early years of chemical evaluation and classification, would necessarily contain the majority of new chemicals. The designation of Category IV would be assigned to chemicals which

a. Had received no test evaluation
b. Had received inadequate or incomplete test evaluations

In other words a category IV chemical would be one which had received no official carcinogenicity assignment.

Such a designation is necessary so that labour, management, industrial hygienists and other concerned groups do not confuse untested or incompletely tested chemicals with those defined in category II i.e 'substances about which there is some uncertainty as to their carcinogenicity.'

2. I would also like to suggest that the advisory council should press the requirement for a provision similar to that covered by Section 8E of the U.S. Toxic Substances Control Act, 1976.

This section reads:

8e) Notice to administrator of substantial risks - Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or environment shall immediately inform the Administrator of such information.....

This topic is mentioned under "issues for consideration" #3 in the discussion paper. I believe I am correct in stating that in the U.S. Section 8E of TOSCA applies to all chemicals, new and old, without consideration of the quantities in which they are produced, imported or consumed.

I have been given to understand that of all the complex demands of TOSCA, this particular provision has served effectively to rapidly set evaluation systems into motion once a possible workplace carcinogen has been identified. I would suggest that a similar system in Canada would prove equally valuable for the protection of occupationally exposed individuals.

I hope you will find these comments helpful.

Sincerely

David M Halton.

David M Halton PhD
Project Scientist
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1982 10 14
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J F Mustard MD
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Dear Dr Mustard

Thank you for sending me a copy of the Report of the Special Advisory Committee on Carcinogens together with council's Discussion Paper on the Regulation of Workplace Carcinogens. Both documents are of the exceptionally high quality I would expect from the Committee.

The Discussion Paper outlines a logical method of regulating carcinogens in Ontario workplaces. The recommended procedures are similar to those adopted by the European Economic Community (EEC) for control of toxic substances. The EEC approach is to require evidence of safety (submission of a base set of toxicological information) before use is authorized. This can be contrasted with the approach taken in the Toxic Substances Control Act (TSCA) administered by the US EPA in which the EPA must provide evidence of hazard before a chemical can be regulated. The safety-based approach as recommended by the Committee has the advantages of encouraging testing early in the development process and of requiring much less governmental resources.

In this regard there is a sobering analysis of the limitations of TSCA in the Office of Technology Assessment (OTA) report of 1981, "Assessment of Technologies for Determining Cancer Risks from the Environment". According to the report, test data need not be generated to support a premanufacturing notice under TSCA. Consequently the EPA needs a very large staff (estimated at 1500) to do the hazard evaluations which are required before toxicological testing can be demanded. In contrast only about 400 persons are employed in toxicological evaluation and regulatory activities in the EEC.

Short-term testing has become an effective means of limiting the introduction of potentially carcinogenic chemicals into the workplace. According to the OTA, since the introduction of TSCA no new chemical has been introduced which had been found positive in short-term tests. Apparently the risks of possible product liability are too high. However, since manufacturers need not perform short-term tests some hazardous chemicals may have escaped this net.

The Committee has recommended the assignment of chemicals to one of three categories.

Category I	confirmed carcinogens
Category II	suspected carcinogens
Category III	non-carcinogens

I have some concern about the use of these designations. The designations apply to the degree of evidence and not necessarily to the degree of hazard or risk. I suspect that Category II could be a catch-all for a large number of chemicals which do not clearly belong in the other categories. These chemicals could vary greatly in evidence and degree of hazard. These "suspected carcinogens" will inevitably be compared and confused with the "industrial substances suspect of carcinogenic potential for MAN "of the American Conference of Governmental Industrial Hygienists (ACGIH) which correspond to Category I. It may be preferable to rename Categories II and III to prevent confusion.

Essentially, Category II contains substances which have been identified as possible carcinogens, predominantly on the basis of structural analysis, short term test results or inconclusive animal assays. These substances may be designated "substances under evaluation". This corresponds to the IARC designation "inadequate evidence of carcinogenicity".

The committee recognizes that there is scientific judgement involved in assigning a substance to

Category III. It could contain substances for which there is strong evidence of non-carcinogenicity or for which the risk of carcinogenicity is judged to be negligible. These substances may be called "substances posing negligible risk of carcinogenicity" rather than "non-carcinogens". This could allow moving substances from category II into category III on the basis of a risk assessment without having to discount fully the existence of a test result. Category III could then be more flexible.

In any event the regulations established for a substance depend on the assessed risk and are independent of the category.

The Committee has proposed setting stricter standards for new plants than for ones currently in operation. I feel that it is preferrable to set a single exposure limit applying to all industrial uses. This limit could be modified by temporary exemptions to current plants. Exemptions could be granted for varying periods of time based on implementation of engineering controls and a risk assessment of the effects of the higher exposure on the population of workers. This would not discourage construction of new facilities, would publicly identify plants which fail to meet exposure limits, and could encourage worker involvement in setting up methods to reduce exposures and work toward the limits.

For new plants it may be specified that evaluations and exposure limits must be available for all substances to be used or made.

A data bank of information on carcinogens is essential if carcinogens are to be regulated in a systematic way. In the Discussion Paper the Committee suggests that assembling and co-ordinating the available data be carried out in a nationwide program through agencies such as the federal Department of Labour, the Department of National Health and Welfare and the Canadian Centre for Occupational Health and Safety.

Relevant information can be gathered at several levels. A basic data bank could consist of all publicly-available information on carcinogens: the development of this resource is planned by the Canadian Centre for Occupational Health and Safety.

Other data banks such as that of the Poison Control Program contain confidential information from manufacturers which cannot be made public. For purposes of regulation of new chemicals, an agency would have to possess regulatory power in order to compel submission of information by manufacturers. Determination of appropriate Canadian national or provincial agency(s) for this task is extremely difficult. For example, designation of the Canadian Centre for Occupational Health and Safety as the national agency would require a regulatory status which it does not now have and which may not be appropriate to its overall function.

As recognized by the Committee, international cooperation is also needed. Considerable negotiation will be needed in this area. The major relevant international bodies are probably the International Labour Organization and the World Health Organization through the International Agency for Research on Cancer, the International Program in Chemical Safety and the International Register of Potentially Toxic Chemicals.

Thank you again for providing me with an opportunity to comment on the Discussion Paper. I look forward to the incorporation of its principles into actions for the further protection of Ontario workers.

Yours sincerely

Robert Whiting

Robert Whiting PhD
Project Scientist
Material Hazards

RW:nw

cc Gordon Atherley
Bill Louch

**The
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November 22, 1982
File 11.5.3

J F Mustard, MD
Chairman
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Dear Dr Mustard:

We are pleased to enclose herewith CCPA's written submission concerning the Report of the Special Advisory Committee on Carcinogens and the Discussion Paper concerning the Control of Workplace Carcinogens.

We are also pleased to confirm that we have reserved January 11, 1983 for CCPA's oral presentation to the Advisory Council. We are awaiting confirmation of the time and place for this presentation from your office.

CCPA will be represented at the oral presentation by the following individuals:

1) W A Neff, Director, Technical Affairs, CCPA
2) W J Martin, Medical Services Director, Cyanamid Canada Inc
3) V A Barker, Director, Occupational Hygiene, Gulf Canada Limited
4) A toxicologist from a member company, to be confirmed.

We trust this is satisfactory.

Yours truly,

Jean M Bélanger

Jean M Bélanger,
President.

The Canadian Chemical Producers' Association

November, 1982

FOREWORD

The Canadian Chemical Producers' Association (CCPA) represents 65 manufacturing companies which produce more than 80% of Canada's total output of industrial chemicals and synthetic resins. CCPA defines the industrial chemical industry as comprising manufacturers whose principle activity involves the chemical transformation of basic hydrocarbon and mineral resources promoted by a chemical, thermal, electrical or catalytic process. With an annual output valued at over $9 billion, the industry directly employs 30,000 people. A brochure describing the Association and listing its member companies is enclosed for your information.

One of the purposes for which the CCPA was established is to advise government on behalf of the Canadian industrial chemical industry. The chemical industry takes a back seat to no one in its desire to ensure that chemicals are properly and safely handled in all phases of their use and the industry's record demonstrates that it has a history of developing high standards of occupational health and safety.

The chemical industry is committed to taking every practical precaution towards ensuring that its operations and the use and ultimate disposition of its products do not present a risk unacceptable to its employees, customers, the public or the environment. It supports the development of equitable, workable and attainable standards and believes the best way to protect the health and well-being of Canadians and their environment is to ensure that guidelines and regulations established by governments:

a) are based on scientifically supportable data and/or expert opinion;
b) are realistic in terms of societal cost/benefit considerations; and
c) preserve the justified confidentiality of proprietary information.

Major areas of interest to CCPA are kept under constant review by the various committees of the Association. One such committee is the Occupational Health Committee which is charged with the continuing task of maintaining and improving the effectiveness of occupational health programs within the chemical industry in Canada. This Committee is made up of industrial occupational physicians, occupational hygienists and managers, and has access to experts in other fields such as toxicology. We believe that it is second to none as a resource for technical expertise in the field of occupational health. The comments set forth in this brief have been carefully reviewed by the members of this Committee.

INTRODUCTION

CCPA has studied with interest the Advisory Council documents concerning carcinogens. The chemical industry recognizes the complex issues which must be addressed when approaches to identifying and classifying chemical substances are considered. We in the industry are attempting to deal with these difficult issues, and we commend the Advisory Council for its thought-provoking background information and proposals.

We do not intend to comment upon the *Report of the Special Advisory Committee on Carcinogens*. We consider this to be a well-researched and lucid report although we may not totally agree with all the views it contains.

Our comments in this brief are confined to the discussion paper which accompanies the report. We feel that, in many respects, the discussion paper departs from the careful and reasoned foundation established in the report.

GENERAL COMMENTS CONCERNING THE DISCUSSION PAPER

Before dealing with specific issues, we feel it is essential to express, at the outset, our basic philosophical difference with the very basis of the approach suggested in the draft discussion paper. The suggested approach is to establish a system to identify, classify and control substances in the workplace which are carcinogens or suspect carcinogens. This mechanism would be separate from, and in addition to, the mechanisms which already exist pursuant to the Occupational Health and Safety Act, 1978 (the Act).

We submit that the discussion paper does not establish a sound basis for developing this new and separate system. The introduction to the discussion paper states that the reasons for choosing carcinogenic substances for special consideration are complex. It then goes on to canvass issues such as fear of cancer, prevention through control of exposure and the relatively recent development of techniques for assessing potential carcinogenicity of substances. We agree these are important considerations which must be addressed in any system aimed at minimizing the risk of individuals developing cancer because of exposure to workplace carcinogens. We do not agree, however, that these considerations necessarily lead to a new and separate policy for dealing with carcinogens in the workplace.

We submit that the Ontario Ministry of Labour already has a comprehensive legislative framework, supported by regulations which are in place or under development, which adequately identifies, classifies and controls chemical substances in the workplace. The legislation is relatively new and the manner in which it will operate in practice is still evolving since all of the provisions of the Act have not yet been fully implemented through regulations. We understand that the Ministry has purposely established a policy of consultation and careful evaluation before issuing regulations dealing with various aspects of the Act. We support this approach. We also understand that the policy which will further implement the legislation concerning reporting and assessing new chemical substances is now under development. Once this policy has been finalized, we believe that Ontario will have a system fully capable of dealing with all new chemical substances in the workplace.

The cornerstone of this system is Section 21 of the Act. This section requires that the Ministry must be notified of new chemical substances in writing and, if the Ministry deems that it is warranted, a report or assessment of the new chemical substance must be made at the expense of the reporting company. Once the Ministry is fully satisfied with the information provided, it also has the power pursuant to the legislation to control exposure if this is warranted. This can be accomplished by either of two methods. First, exposure criteria can be set for potentially harmful agents and substances. In fact, the Ministry has already drafted a preliminary booklet which includes exposure criteria and other helpful information for all persons involved in the administration of occupational health and safety programs. CCPA has submitted comments concerning this draft booklet.

If an exposure criterion is not sufficient in itself for control purposes, the Ministry also has the power to designate particular substances. The Ministry has already exercised this power for several substances, some of which are known or suspect carcinogens.

We submit that this comprehensive and closed system, aimed at all new chemical substances, stands by itself and an entirely separate policy aimed solely at carcinogens need not be superimposed upon it. Section 21 provides the means of *identifying* and *assessing* cancer risks associated with new chemicals. Companies are already complying with its requirements. The Ministry then has the power to *control* exposure by means of exposure criteria or designation.

Our support for the existing legislation and regulatory framework does not imply, however, that we feel no improvements can be made to the system. As we comment on the specific issues listed in the discussion paper, we will raise and discuss particular issues and strategies which we feel should be considered within the framework of the Ministry's existing and developing policy.

We also recognize that our general comments deal only with new chemicals. Our understanding, based on the covering letter which accompanied the Council's documents, is that the Ministry's charge to the Advisory Council was to "address the matter of new chemicals in relation to carcinogenicity". In some of its proposals, the discussion paper goes beyond this mandate and considers existing chemicals as well. We will comment upon these specific proposals in the next section of this brief.

Since we do not support the separate regulatory system aimed specifically at carcinogens, it goes without saying that we do not support the wholesale expansion of this system into identification, testing and control of other chemical substances.

We have requested the Advisory Council to arrange for an oral presentation by CCPA spokesmen to supplement this brief since we believe carcinogen policy development is extremely complex, encompassing issues which are rapidly developing as research reveals new knowledge. It is not possible to fully address these issues, which are both scientific and sociopolitical, in a written submission. We feel much more ground can be covered in a dialogue between interested and informed individuals. This is one of our reasons for requesting an oral presentation.

SPECIFIC ISSUES LISTED IN THE DISCUSSION PAPER

In this section of our brief we will deal with each of the specific issues listed in the discussion paper. For ease of reference, we will follow the same numbering system used in the discussion paper. In following this approach, however, we do not wish to omit comments concerning the text which precedes the issues listed in the paper. Accordingly, before addressing the issues, we wish to comment on matters in the text as follows:

- Throughout the text of the discussion paper, there is reference to "chemicals", "substances", "chemical substances". These terms appear to be used interchangeably throughout the discussion paper and none of them are defined. As a result, various sections of the paper are difficult to understand.

- We take exception to the blanket statement that few cancers can be cured. Experience has shown that many cancers can be cured and that the success rate increases the earlier that diagnosis of the cancer takes place.

- We believe that the discussion paper fails to adequately distinguish between the effects of ionizing radiation and chemical substances in the production of human cancer. Ionizing radiation penetrates tissues to target cells and can, therefore, have a direct effect. Chemical substances, on the other hand, will often be subject to biotransformations, resulting in active metabolites which in many cases are the probable carcinogenic agent.

- The paper suggests jumping immediately from tissue accumulation of a new substance to long-term animal testing. In our view, there is a misplaced emphasis on tissue accumulation. It is not always a best measure of potential carcinogenicity. Some substances do not accumulate in tissue and yet they are potent carcinogens.

- The section of the text dealing with testing is imprecise and unclear. We suggest greater emphasis should be placed upon testing as an iterative process where the result of one test provides the basis for requiring additional tests. The three-level approach to testing suggested in the report (consisting of short-term *in vitro* tests, short-term *in vivo* tests and animal bioassays) should be more fully developed in the discussion paper. Since the discussion paper fails to deal with this aspect of testing, it places little importance upon the results of short-term tests in the proposed classification system. Where the paper refers to results from two short-term tests, it should specify that these are results of two *different* short-term tests. Positive results from, for example, two salmonella bioassays should not by themselves form the criteria for requiring an animal bioassay.

CCPA is in the process of developing a position paper dealing with all aspects of toxic chemical legislation. We hope it will be finalized in time so that it may be discussed with Advisory Council members during CCPA's oral presentation which will supplement this brief.

ISSUE # 1 — NATIONAL AND INTERNATIONAL CO-ORDINATION AND CO-OPERATION IN THE CONTROL OF CARCINOGENS

1. CCPA has consistently supported proposals to harmonize initiatives from the various levels of government whenever this is feasible. We do not support, however, a single nationwide carcinogen program which might not

be appropriate in all instances. Rather, we visualize a co-ordinated general policy which could be incorporated into the existing or developing programs of various governments and agencies.

For example, Environment Canada is currently studying legislation governing the testing of new chemicals. As we have already discussed, the Ontario Ministry of Labour has the power to require testing of new chemicals. We urge that testing requirements developed by various levels of government and agencies in Canada be consistent so that the manufacturer basically is required to produce one data set to satisfy most requirements using proper test procedures and laboratory techniques of his own choice.

In our view, the preferred testing system would be modelled on that of the United States' Toxic Substances Control Act (TSCA). There is an inherent flexibility in that system since no tests are prescribed. The producer/importer of the new chemical must demonstrate that it does not produce an unreasonable risk to health and the environment. This means that the choice of the tests to be done (plus supporting arguments for that choice) is the responsibility of the producer/importer in consultation with the responsible authority. If the Advisory Council wishes, a more complete description of this system can be provided during CCPA's oral presentation.

We recognize, however, that some differences among the objectives of various governments and agencies will always exist and require some variation in the data that must be submitted. For example, the potential for exposure to a given substance in the workplace frequently differs significantly from the potential for exposure elsewhere. This may result in somewhat different data being required for occupational health and safety purposes as compared to protection of the environment. We would support a nationwide program to co-ordinate testing requirements consistent with such varying objectives of the governments and agencies involved. Assessment of carcinogenicity (which need not imply actual testing for the majority of new chemical substances) would be one aspect of this overall program.

2. In our view, the group convened to co-ordinate chemical testing should prioritize its own objectives in establishing a national testing program. Assessment for potential carcinogenicity would be one important aspect of this program.

3. We suggest that the best data available from all sources should be considered in setting priorities and exposure limits. We would expect that sources such as existing legislation in other countries and various international agreements would be thoroughly and critically reviewed. These sources should provide many worthwhile insights. We doubt, however, that any one of these sources would be wholly suitable for adoption in Ontario.

ISSUE # 2 — ADVISORY COMMITTEE(S)

We believe that the Minister should assess the advice he now receives concerning regulatory programs and decide whether there is a need for additional advice. If the Minister should decide that an advisory committee on identification, testing and control of chemical substances would be of assistance to him, we would recommend that the committee be an independent body consisting of appropriately qualified experts from various fields of science. The mandate of this committee should be limited to advising with regard to principles for testing programs for chemical substances, control of exposure and other scientific issues. As we have previously recommended, testing programs for specific chemicals should be flexible and should remain as a matter between the government or agency and the manufacturer. Representatives of CCPA member companies would be pleased to participate in such an independent committee.

If a group is convened to co-ordinate chemical testing on a national basis (as proposed in Issue 1), then this advisory committee should have a means of input to that national group.

ISSUE # 3 — REPORTING REQUIREMENTS FOR NEW CHEMICALS

In our opinion, the reporting requirements suggested in the discussion paper already exist in Ontario pursuant to Section 21 of the Act. CCPA supports full disclosure of all available relevant information to the Ministry so long as a satisfactory confidentiality policy is in place. The chemical industry recognizes its responsibility to work with government agencies to formulate, implement and maintain procedures which protect both human health and the environment. With this in mind, the industry is prepared to divulge confidential business information to government, provided that this information is fully safeguarded by government. Such safeguarding is required to protect the competitive advantage an individual company may have achieved over a long period of time and at considerable expense.

It may be of interest that CCPA has worked with the Ontario Ministry of Labour to assist in its development of such a confidentiality policy. Our thoughts concerning a satisfactory confidentiality policy will be more fully expressed in the oral presentation which accompanies this brief.

As for reporting requirements for new chemicals to be marketed in limited quantities, CCPA would be interested in working with the Ministry to develop an appropriate mechanism to accomplish this. We have some difficulty in supporting a "one tonne rule" if it implies that volume may be used as a surrogate for exposure. Such a rule may be valid when aimed at exposure in the marketplace but the possibility of exposure in the workplace could be significantly higher.

We stress that the fundamental issue is safety of workers which requires an exposure assessment. Accordingly, we suggest that any rule developed should be applied to each substance on an individual basis. If less stringent testing is agreed upon for some substances, a reasonable assessment based on the characteristics of the particular substance should still be required.

ISSUE # 4 — TESTING REQUIREMENTS FOR NEW CHEMICALS

We understand that the Ministry is currently analysing its policy for testing of new chemicals pursuant to Section 21 of the Act. This policy could be formalized by means of regulation. As we have already indicated, we urge that this policy be based upon the flexible approach taken by TSCA. If the Minister decides that additional testing is required for a particular substance, the means for achieving this is built into the existing system.

In this testing program, examination of the new chemical on the basis of its chemical structure and relationship to known carcinogens is one part of the initial assessment of the new chemical. We stress that this step is only one part of a comprehensive assessment which cannot be considered conclusive in itself. A number of other factors, including exposure, must also be considered in this initial assessment.

ISSUE # 5 — TESTING PROCEDURES

1. We would be pleased to work with the Ministry in developing a flexible testing program for the purpose of Section 21 of the Act. Assessment for carcinogenicity would be one aspect of this program.

2.a. In our opinion, this procedure, which is based on the maximum tolerable dose concept, is now outdated. We suggest that the Ministry should consider the more modern procedure suggested by bodies such as the World Health Organization, the Organization for Co-operation and Economic Development, and the United States' Environmental Protection Agency. These latter procedures give due consideration to pharmaco-kinetic aspects.

b. If warranted by the initial assessment of a substance and the possibility of exposure, we would support an iterative testing program for determining the potential carcinogenicity of new substances. The first level of testing for carcinogenicity would consist of short-term *in vitro* tests, the second would be short-term *in vivo* tests, and the third level would be the animal bioassay.

c. We support the testing of commercial samples wherever this is possible. It should be recognized, however, that commercial preparations are not always available at the time testing must commence.

d. We suggest this question clearly illustrates one of the problems associated with a formal and inflexible testing program. Such a program can only be updated at fixed intervals and it is difficult to choose the correct interval for updating.

In the system which we support, the protocol for testing would be constantly reviewed and updated to properly take account of advances in testing and assay procedures. This system would also inherently permit use of equivalent tests so long as they meet the usual professional standards. This encourages the development of better test methods.

ISSUE # 6 — THE CLASSIFICATION OF NEW CHEMICALS

We recognize that there may be a place for categories and criteria to assist in assessing the information submitted to the Minister pursuant to Section 21 of the Act (eg, data pertaining to toxicity) and in establishing appropriate control mechanisms. We do not agree, however, with the categories which are included in the discussion paper.

We do not intend to list in this brief the many difficulties which we have with these categories. We can briefly mention, however, that in none of the criteria is the terminology "human carcinogen" used. We also point out that the categories offer an enticing invitation to place a great many substances in Category II, unless they have been clearly confirmed as belonging in Category I.

In our opinion, too little is known concerning carcinogencity to permit broad classification at this time. As a result, we believe that the best approach is the exercise of reasoned professional judgment on a case-by-case basis. In exercising such judgment, the focus should be on the performance of substances in various tests rather than on the tests themselves.

We believe that the Advisory Committee, the creation of which we have supported under Issue 2, and in which we have offered to participate, would be able to develop more suitable criteria than those offered in the discussion paper.

ISSUE # 7 — THE CONTROL OF NEW CHEMICALS

1. We wish to re-state and emphasize that we do not agree with the categories set forth in the discussion paper. We stress that exposure must be considered along with toxicity whenever regulation of a substance is proposed. Even if a substance is a known human carcinogen, there may be no need for regulation if there is no likelihood of exposure.

If, on the other hand, there is a potential for exposure, regulation by either the establishment of appropriate exposure criteria or designation should be considered. In determining the appropriate regulatory response, a complete toxicological assessment should be made and a risk assessment (including a physiological assessment) should be performed. Factors such as potential exposure and potential carcinogencity would be important components of this overall assessment.

2. Each of these cases should be thoroughly evaluated on an individual basis. Where exposure can be suitably controlled, use of the substance should be permitted. In addition, we point out that the substitute material should be properly tested and its exposure evaluated. It is regrettable that in some cases problems have occurred due to the rush to replace substances by substitutes which were not fully investigated.

3. Rapid advances in analytical methods have made it impossible to achieve "no detectable exposure" since this is a target which is constantly shifting. Accordingly, permissible exposure limits should be set for all materials based on their potential health effects.

4. We repeat that the category should be properly defined. We do not agree with the definition of Category II.

5. Refer to our answer to 3. above.

6. Where they are practical and appropriate, engineering and workplace controls are effective in meeting appropriate standards. We point to the designated substance regulations as examples of this.

7. Personal protective equipment should be used in conjunction with engineering and workplace controls. Again, we draw your attention to the procedures set forth in the designated substance regulations.

8. Occupational health surveillance should be maintained for all workers, including surveillance of exposure or potential exposure to all hazards.

9. Yes, with the qualification that evaluation of the need for occupational health surveillance should still occur on a routine basis.

ISSUE # 8 — THE TESTING AND CLASSIFICATION OF CHEMICALS NOT CONSIDERED NEW

1. We doubt that this approach is feasible, given constraints upon available resources. A more practical approach might consist of a review of already existing priority lists such as those of the United States' National Toxicology Program, the TSCA priority list and the lists prepared by the Ontario Ministry of the Environment.

2. The substances in the lists referred to above should be re-prioritized based upon use in Ontario, health effects and potential for exposure.

3. Costs should be shared by manufacturers producing the chemical. This is not easily achieved. In some jurisdictions, it has been proposed that the government control agency become involved in equitably distributing development costs of new chemicals. Such a role might be more appropriately reserved for distributing costs associated with chemicals not considered new. We also refer you to the United States EPA system for achieving this. We do not believe that use in a newly-constructed workplace should be a trigger for testing (refer also to Issue 9).

4. We repeat that we are not satisfied with the classification system proposed in the discussion paper. Accordingly, we believe the most urgent issue is development of a more practical system in which reasoned professional judgment would have an important role. However, once this system is in place, we agree in principle with a review of the EPA list. We point out that this would be a tremendous task and probably no single jurisdiction has the resources to complete it. Testing performed in other jurisdictions will have to be relied upon in large part.

ISSUE # 9 — THE CONTROL OF CHEMICALS NOT CONSIDERED NEW

We have already answered all these questions in dealing with the other issues. We recognize that engineering controls are easier to fit in new plants and they may be more effective in such plants. Construction of a new plant is also an easy administrative trigger for various purposes. We believe, however, that workers should be equally protected in both existing and new plants, recognizing that the means of achieving this may vary with the age of the plant.

ISSUE # 10 — EPIDEMIOLOGICAL SURVEILLANCE

1. Following a thorough assessment, epidemiological surveillance should be provided where it is deemed appropriate. As the question implies, such surveillance would not be needed where there is no significant exposure.

2. Such records should be maintained where the thorough assessment suggested in 1) above has demonstrated that epidemiological surveillance should be provided.

3. Yes.

ISSUE # 11 — THE PROVISION OF INFORMATION TO THE WORKFORCE AND TO THE PUBLIC

1. The Ministry should ensure that the employer provides the appropriate information to protect the worker. This should be accomplished, however, in a manner consistent with a satisfactory confidentiality policy. For example, in some cases chemical names and specific uses are considered confidential business information. This is because specific chemical names can reveal proprietary formulations that are the result of an individual company's expensive and time-consuming research and development.

Disclosure of chemical names to joint health and safety committees will do little, if anything, to advance the protection available to workers. Information relevant to health effects, on the other hand, is not so commercially significant that it requires confidential handling. Accordingly, information such as precautions to use, physical/chemical data, and summaries of toxicology and ecotoxicology studies should be made available to the joint health and safety committee. These concepts will be more fully developed in the oral presentation accompanying this brief.

2. Refer to the answer to 1. above.

3. A federal-provincial task force and a CSA technical committee are both working to develop just such a system. The Ministry of Labour should continue its participation in, and support for, these endeavours.

4. While we fail to understand the function of the Ministry of Labour in providing data to the public (as opposed to workers), we can see that such a data base providing information in summary form only might be appropriate.

5. We support disclosure of information to the extent that it is necessary to protect workers. This disclosure should be consistent with both Section 34(1)(b) of the Act and the confidentiality policy under development by the Ministry. The information disclosed should also be made available in a form readily understood by workers.

As we have already explained, there are valid reasons for maintaining the confidentiality of some information. The reasons for this will be more fully explained in our oral presentation.

ISSUE # 12 — PENALTIES FOR NON-COMPLIANCE WITH THE REGULATION

We see no reason to treat such a violation any differently than other serious instances of non-compliance with the Act.

ISSUE # 13 — RESEARCH

We support some relaxation of regulatory requirements for research and development, so long as the health and safety of the employee is maintained. In the initial phases of development of a new chemical, up to and including the pilot plant phase, the potential risk (ie, the probability of a hazardous event occurring) is significantly less than when full commercial production begins. It is only at the full commercial production phase, on the other hand, that return on development costs begins. Any regulatory requirements which unnecessarily increase costs prior to this phase will have a very damaging effect on the innovative process.

Research always involves unknown risks. However, those involved in research are better trained to deal with these risks and they operate under constant and direct supervision.

CONCLUSION

In conclusion, we wish to thank the Advisory Council for the opportunity to comment upon the report of the Special Committee and the discussion paper.

Our position can be summarized as follows:

- The existing system provided by the Occupational Health and Safety Act and accompanying regulations is sufficient to address the issue of new substances in the workplace (including carcinogens).

- This system consists of Section 21 of the Act for the purpose of *identifying* and *assessing* new substances supported by the power to develop exposure criteria or to designate for the purpose of *control*.

- We believe a flexible system should be adopted for the purpose of Section 21 of the Act.

- We support national consistency in testing programs for new chemicals, and would be pleased to assist in achieving this goal.

The Canadian Manufacturers' Association

L'Association des manufacturiers canadiens

One Yonge Street, Toronto, Ontario M5E 1J9
(416) 363-7261 Telex 065-24693

October 18, 1982.

The Chairman,
Advisory Council on Occupational Health
and Occupational Safety,
400 University Avenue,
TORONTO, Ontario,
M7A 1T7.

Dear Sir:

Enclosed please find a copy of the submission prepared by the Ontario Division of The Canadian Manufacturers' Association concerning the Discussion Paper, "The Control of Workplace Carcinogens".

Yours very truly,

Anneli Talvila

Anneli Talvila,
Industrial Relations Advisor.

AT/ph
encl:

VANCOUVER TORONTO MONCTON
EDMONTON OTTAWA CHARLOTTETOWN
WINNIPEG MONTRÉAL HALIFAX
CMA GETS THINGS DONE

The Canadian Manufacturers' Association Ontario Division

October, 1982

The Ontario Division of The Canadian Manufacturers' Association welcomes the opportunity to comment on the Discussion Paper, *The Control of Workplace Carcinogens* prepared by the Advisory Council on Occupational Health and Occupational Safety.

The Canadian Manufacturers' Association has requested the Government not to pass regulations in this time of economic difficulties which would add to costs and would not contribute to economic growth. In any case, all regulations should first be subjected to thorough study to determine whether their passage is justified in economic terms.

We have a number of concerns with the approaches outlined in the Paper and hope that the Advisory Council will further review the subject before preparing recommendations for the Minister of Labour.

We have specifically addressed some of the Issues for Consideration listed at pages 20-30 and propose to discuss them under the same headings.

National and International Co-ordination and Co-operation in the Control of Carcinogens

We feel strongly that in the case of an issue as complex as the control of carcinogenicity, a multiplicity of programs should not be established across the nation. To realize cost-effectiveness, programs should be developed on the basis of co-operative federal/provincial effort with appropriate input from international agencies.

With respect to the statement in paragraph 2 to the effect that the Federal Government be encouraged to give the "highest priority" to assembling data on carcinogenicity of chemical substances, we wish to query the justification for focusing solely on carcinogens to the exclusion of toxic effects generally.

Advisory Committee

We believe that the Ministry of Labour should definitely consult at all stages with representatives of interested groups and appropriate sources of technical expertise. A system of continuous consultation among these groups and with other jurisdictions will help to ensure a practical and cost-effective control program. If the proposed Advisory Committee represents technical expertise and interested groups we would support its establishment.

Reporting Requirements for New Chemicals

As section 21 of the Occupational Health and Safety Act has been in effect for a relatively short time, we suggest that it should be allowed to fully develop and form the basis for reporting on all new chemicals.

We are not opposed to a requirement that a manufacturer or importer be obligated to disclose all information in his possession relative to chemical identity, physical properties and results of toxicity tests. As some of this information may be regarded as confidential by the reporting company, the Ministry should ensure that a mechanism is in place to preserve the confidentiality of the information so designated.

We generally agree with the application of a one tonne per annum rule. But where low volume chemicals are known to be toxic we recommend that full reporting requirements should apply also.

Testing Requirements for New Chemicals

We propose that an initial risk assessment be made on a case by case basis. Where the results of such assessments indicate that toxicity data is required, tests should be conducted according to internationally accepted guidelines.

Testing Procedures

We would point out that in the United States testing procedures have not been legislated. Where testing is required, the decision as to what test is appropriate should be left to the manufacturer or importer. We do not feel that legislation of testing procedures is appropriate in view of the developing nature of toxicity testing generally.

The suggested Ontario model containing three categories is far too simplistic. As currently stated, it lacks definition and criteria, but even on the basis of the general outline contained in the Discussion Paper it is clear that the bulk of substances would end up in Category II. To label such a category as suspect carcinogens on the basis that adequate definitive data are not available would be counter-productive. Commercial development of such substances could be retarded or even precluded even though these substances may well be demonstrated subsequently to have no carcinogenic effect. It would be reasonable to label such a category simply "Substances Which Require Testing Before a Definitive Conclusion Can Be Reached". Effective management of this category would require setting of priorities for risk assessment and subsequent testing.

The Testing and Classification of Chemicals Not Considered New

We feel that Ontario should look at American and other jurisdictions' test results. The Government should consult with the Advisory Committee and other jurisdictions in order to tap existing resources.

Where it is considered necessary to test a substance currently in use in Ontario, we agree that the cost of such testing should be borne by the manufacturer but would point out that in certain cases this cost should be borne by the importer of the substance. We feel some concern for established but small companies who may have problems meeting these unexpected costs. Perhaps a postponement of testing or a sharing of costs could help these small manufacturers or importers.

We do not feel that the Ministry should make a systematic attempt to have substances not considered new to be classified within a period of five years.

Rather, we suggest that priorities be set for evaluation on the basis of knowledge gained from our own and other jurisdictions. The setting of an arbitrary time limit is not helpful, considering the state of test results and testing facilities available today.

We do not agree that a chemical to be used in a newly-constructed workplace should automatically be subjected to the testing and classification procedures employed for new chemicals. This would constitute unfair discrimination against a new manufacturer, as opposed to those with existing facilities.

Epidemiologic Surveillance

Because of the lack of epidemiologists and facilities for epidemiologic surveillance of individuals known to have been exposed to established or suspect carcinogens, we do not feel that Ontario should lead the way in being the first jurisdiction to require such surveillance. However, we do agree that employers could be required to establish group and individual exposure records and assignment records suitable for future epidemiologic surveillance.

Conclusion

We feel that carcinogen testing and regulatory requirements should be coordinated nationally and even internationally, so that undue hardship and complexity is not imposed on employers and so that test results achieved in other jurisdictions may be taken advantage of. For this reason, we believe that any final classification scheme should reflect the current state of knowledge concerning carcinogenicity. The proposed three category scheme is highly simplistic. Its final result would be to group most chemicals into Category II so that regulation would not really be facilitated. Furthermore, we do not feel that Ontario should legislate testing procedures; rather, choice in this regard should be left to the manufacturer or importer. Where the Government does not feel that adequate testing has been performed, it is open to them to refuse to allow the manufacture or importation of the substance until further tests have been done. However, with access to testing protocols developed and evaluated by various expert groups in the field, we feel that under the direction of general guidelines, the manufacturers or importers will be best able to determine the appropriate testing procedures for each substance.

City of Toronto
Department of Public Health
City Hall, Toronto, Ontario, Canada M5H 2N2

A. S. MACPHERSON, M.D., M.Sc.,
Medical Officer of Health

Reply Attention: Richard Boehnke
Community Health
Protection

Telephone: 367-7609

October 8, 1982.

Advisory Council on Occupational
Health and Occupational Safety,
Office of the Chairman,
400 University Avenue,
Toronto, Ontario.
M7A 1T7

Re: Discussion Paper on the Control
of Workplace Carcinogens

Dear Sir:

Enclosed please find comments prepared by my Department on the above discussion paper. We are impressed to date with much of the work done by the Advisory Council on Occupational Health and Occupational Safety, but do feel that further cautions in this very important area of workplace safety should be included.

We trust you will find our comments useful.

Yours truly,

Medical Officer of Health.

RHB/srg

Encs.

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City of Toronto
Department of Public Health

October, 1982

The City of Toronto's Department of Public Health welcomes the opportunity to respond to this Advisory Council's discussion paper on controlling and regulating workplace carcinogens.

Our general response to the discussion paper is disappointment that it did not allow for more detailed comment on the Advisory Council's own views on the various aspects of a workplace carcinogens policy. The Department is concerned that, as outlined in the covering letter, the process will provide no opportunity for public comment on the Advisory Council's recommendations to the Ministry. We emphasize that the success of this policy will depend on extensive input from all interested parties. The discussion paper itself recognizes the importance of public input in the context of developing regulations as part of a workplace carcinogens policy. We strongly recommend that significant opportunity for public input be built into the further drafting of this policy.

As we have indicated in an earlier brief to the Ministry, our Department views the creation of a specific policy on workplace carcinogens to be an essential part of any comprehensive occupational health and safety program.

In our opinion the Provincial Government has clear jurisdictional authority to establish and implement this policy. We reject the tone of the argument used in the discussion paper that independent action by the Ontario Government in controlling exposure to carcinogens and suspected carcinogens would have a limited effect and could have potentially serious and disruptive economic implications if the program were not coordinated with other governments (provincial and federal) in Canada. While it is true that strictly speaking, the program would be limited to Ontario, the Department believes it could also have significant positive impact on the health of Ontario residents, regardless of the actions adopted by agencies in other parts of the country. We also seriously question the assumption that a workplace carcinogens policy established only in Ontario will have serious negative economic implications for the province. We know of no evidence to support such a statement.

However we do recognize the importance of coordinating data collection and evaluation with other agencies and government bodies, both nationally and internationally. It is also important to learn from the experiences of other agencies in establishing similar policies elsewhere. However, the Provincial Government has the mandate and jurisdictional power to protect Ontario residents from occupational exposure to carcinogens and it should fulfil that responsibility, as quickly as possible.

The next section of this brief responds directly to specific aspects of a workplace carcinogens policy as described in the Advisory Committee's discussion paper. An area not explicitly covered in the discussion paper was a working definition of a potential carcinogen. This is essential to any carcinogens policy.

We would recommend a working definition along the lines originally set out by the United States Occupational Health and Safety Administration (OSHA) in its carcinogens policy. OSHA defined, a "potential occupational carcinogen" to be, among other things,

"any toxic substance which (i) causes at any level of exposure or dose, as the result of any oral, dermal or respiratory exposure, or any other exposure which results in the systemic distribution of the substance under consideration in the organism tested, an increased incidence of benign or malignant neoplasms, or a combination thereof, in (i) humans or (ii) in one or more experimental mammalian species, or (2) in a statistically significant manner decreases the latency period between exposure and onset of neoplasm in (i) humans or (ii) in one or more experimental mammalian species."

The Department generally agrees with the concept of Advisory Committee(s) to advise the Minister on identifying, evaluating and categorizing substances as to their potential carcinogenicity. The creation of such committees is a useful alternative to the establishment of rigid criteria for evaluating potential carcinogenicity, particularly given the numerous factors that can influence the "conclusiveness" of testing results. A concern we have is that the membership of the Committee(s) reflect the purposes of the Committee(s).

That is a Committee to review and interpret scientific evidence should be composed of scientists familiar with the field; while a Committee to recommend appropriate regulatory actions should be composed of representatives from all the affected parties concerned about occupational exposure to carcinogens.

The Department is also in general agreement with the framework proposed in the discussion paper for identifying, screening and evaluating the carcinogen potential of new substances being introduced into the market. Specifically we agree with:

1. the use of chemical structure and relationship to known carcinogens as a means of identifying substances (specifically organics) which are to be tested for potential carcinogenicity.

2. the use of short term tests and animal tests to identify and assess the carcinogenic potential of new substances.

3. the creation of three categories based on evidence of potential carcinogenicity.

4. the creation of an Advisory Committee with scientific expertise to assist the Ministry in evaluating the evidence.

5. the principle that all substances being used in a new plant should be automatically subjected to the same testing and classification procedures as employed for new chemicals.

6. mandatory reporting requirements being established relating to the disclosure of evidence indicating the potential carcinogenicity of a substance to be manufactured or imported.

7. the need for periodic reviews of testing requirements (three years being a reasonable time frame).

8. regular publication of the lists of substances which have been evaluated and placed in the designated categories.

However we are disappointed with the brief treatment given in the discussion paper to screening of substances already in use. While the discussion paper recognizes the need for establishing a process to identify and classify the large number of substances reported or alleged to be carcinogenic, it does not suggest a system to do this. Nor is there any suggested process for setting priorities among the substances requiring further testing for carcinogenic potential. In our view, the creation of an explicit framework of this kind would improve the efficiency of the regulatory process by (hopefully) ensuring that the most serious carcinogenic hazards are dealt with first.

We recommend that any process for screening and evaluating the carcinogenic potential of substances now in use should include the creation (with public input) of a 'Candidates List' of substances which on the basis of a brief scientific review, might be considered candidates for further review and possible identification and classification of potential carcinogens.

The Department also favours the establishment of a specific time frame to properly test and categorize all substances now used in Ontario for their potential carcinogenicity; five years seems reasonable. Collaboration with other agencies would be useful in speeding up the evaluation process. We recommend that a mechanism for assessing progress towards the 5 year goal be added as a means of determining the realistic nature of this time frame.

Our final comments concern the establishment of appropriate regulatory measures. The Department recommends that as a general rule regulatory controls should be decided by an Advisory Committee whose members represent the major sectors (labour, business, etc.) from the industries affected by the regulatory action.

As a Public Health Department, we also recommend the following principles be adopted in creating regulations for specific substances:

- For new substances or presently used substances in new plants, the regulations should be based on the principle that no level of exposure is permitted for substances placed in Category I or II. Regulation priorities should be firstly substitution of a less toxic substance for the potential carcinogen; and secondly the use of *engineering design* for control exposure. If substitution is not possible for Category II substances, exposure should be reduced to as low as feasible.

- For substances already in use, regulatory action should be taken for both Category I and II substances. During the initial evaluation period (proposed as 5 years) these substances should be regulated on the principle that exposure is as low as is feasible; with regulatory priorities being *substitution* with a less toxic substance and engineering controls. Personal protective equipment should *only* be used in time limited emergency situations.

We recommend in addition that the aim of the program should be to have all substances now in use which are placed in Category I or II with the same regulatory controls as new substances by the end of the initial evaluation period (proposed to be 5 years). This should be explicitly stated in the policy.

Concord Scientific Corporation
2 Tippett Road, Downsview (Toronto), Ontario, Canada M3H 2V2
Tel. (416) 630-6331

October 5, 1982

Our Ref. #: 101.G56

Dr. J.F. Mustard, Chairman
Advisory Council on Occupational
Health and Occupational Safety
400 University Ave.
Toronto, Ontario
M4A 1T7

Dear Dr. Mustard:

Re: Discussion paper: "The Control of Workplace Carcinogens"

I am writing in response to your invitation of June 30, 1982 to comment on the Council's Discussion Paper of the above title.

The thoughts expressed here are my personal reaction to the issues raised in that paper. My response is based on my professional experience in the assessment of both environmental and occupational exposures to toxic substances. This experience has been gained in the initiation and development of the Ontario Government's Hazardous Contaminants Program, in serving as chairman or member of several Ontario Government inter-ministerial working groups on exposure to workplace and environmental contaminants, in co-operative federal-provincial programs respecting environmental contaminants, and in research related to monitoring, effects and screening of toxic substances in the environment and the workplace, carried out in academia, government service and private consulting.

With this perspective, I wish to comment on two broad topics that are addressed by the Discussion Paper: legislation and jurisdiction for the regulation of toxic substances (specifically, carcinogens), and the advisability of a special program to control the "carcinogens" sub-set of toxic substances in the workplace.

It is my belief that the control of carcinogens (or any toxic substance) will be more effective if it is addressed in a societal context, rather than in the context of a single compartment, such as the workplace.

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That is, since workplace chemicals end up in consumer products, are transported across the country (and across international boundaries), and are discharged to the environment (with both ecotoxic and community health implications), there is much to be gained by assessing and regulating chemicals as potential multicompartmental contaminants. Very few toxic substances are found only in the workplace, and in the case of carcinogens, for which low-level, chronic exposure may be causative, community exposures may (probably in a few cases) have more significant effects on morbidity or mortality.

I would argue in favour of the co-ordinated approach taken in the U.S. to administer the Toxic Substances Control Act by forming the Interagency Regulatory Liaison Group (IRLG). This approach recognizes the multicompartment impact of toxic substances by involving the departments responsible for regulating all routes of human and ecosystem exposure to chemicals. The work of the IRLG appears to expedite and focus the assessment and control of exposure to chemicals efficiently.

Similarly, Canada's Environmental Contaminants Act should be able to support some of the requirements of controlling workplace toxic substances. For example, section 4(6) of the Environmental Contaminants Act already specifies mandatory reporting of toxicity information for new uses of chemicals (manufacture and importation) in excess of 500 kilograms (one-half tonne) per year. Presumably, regulation under chapter 21 of the Ontario Occupational Health and Safety Act (1978) - or as may be amended by Bill 110 - would be most effective if co-ordinated with such existing requirements in Canada. As an aside, why propose a 'one-tonne rule' when a 'one-half-tonne rule' already appears in Canadian legislation?

In this context, it seems to me that since most exposure of Canadian workers to toxic substances will be to substances manufactured in Canada or the U.S., close co-operation under the provisions of existing legislation in these two countries will have a more positive effect on the health of Canadian workers (and the Canadian population in general) than broader international conventions. Obviously, global co-operation in information gathering is essential, but control will be executed under Canadian federal and provincial law, and primarily the latter, since the federal government has no mandate in occupational health other than federal facilities.

The main point of this portion of the discussion is that the Council would be advised to address the issues in the context of the options available under existing legislation. An *a priori* assessment of control requirements is a laudable exercise, but if it leads to recommendations for the development of legislation (or regulation) that do not take into account the opportunities offered by current mandates, needless duplication and considerable wastage of time in drafting, evaluating and promulgating new legislation will result. The latter exercise, inescapably, takes years.

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Secondly, I question both the advisability and necessity of developing specific policy restricted to the control of carcinogens. Many toxicological endpoints other than carcinogenesis that may also arise from chronic, low-level exposure to toxic substances (or from acute exposures, for that matter) are probably equally as significant in their overall effects on the health of Canadian workers. The total impact of teratogenesis, fetotoxicity, mutagenesis, neurotoxicity, and so on, that may arise from occupational or (less likely) environmental exposure to toxic substances may be, in reality, more insidious with respect to total societal cost and personal anguish than is now perceived for carcinogenesis.

I doubt that a policy regarding occupational carcinogens, developed in isolation from the endpoints cited above, and in isolation from consideration of other exposure pathways, will have a significant and lasting effect on the health of Canadians. A chemical-by-chemical approach to regulating "carcinogens" also fails to recognize the multi-factorial nature of cancer (and some of the other endpoints referred to above).

If the Council perceives that the issue of carcinogenesis is an emotional one (as outlined on page 1 of the Discussion Paper), then, it seems to me, your role as scientists is to continue to point out that fact, and to continue to stimulate development of the means to bring about better public (including workers) understanding of the subtlety and complexity of the issue. In my view, the entire spectrum of possible disease endpoints that may arise from exposure to certain chemicals under certain conditions (not all chemicals and not all conditions) should be addressed in such an education program and of course, in research and regulatory development programs.

Oversimplification of complex realities, so that single issues such as carcinogenesis may be addressed in seeming isolation, will not likely have a positive effect, once an increasingly sophisticated public recognizes the oversimplifications as such.

In the context of the opinions that I have expressed, I would hope that the Council would have the courage to recommend against rushing to develop a control strategy limited to occupational carcinogens. The long term benefit to occupational, environmental and community health would be enhanced by addressing complexity and ubiquity directly, rather than simplifying and compartmentalizing them.

An individual's personal opinion, admittedly, cannot consititute a public policy. Based on our corporate experience with industrial workers and their organizations, however, there does not seem to be an overwhelming and specific concern with carcinogens (except for certain agents or industries), as compared with toxic chemicals generally, or more broadly with achieving employer priority for comprehensive occupational health and safety programs. The Council could make a much greater contribution to lowering

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cancer mortality of workers (and general public alike) by recommending a serious and active campaign to decrease the level of cigarette smoking among workers than could ever be realized by control of "occupational" carcinogens.

There is a perceptive article on this subject (i.e., the author's point-of-view agrees with mine) by Dr. Gori Batta Gore, formerly of the U.S. National Cancer Institute, in the September 6, 1982 issue of Chemical and Engineering News.

I have enclosed my résumé and list of publications to help you evaluate the weight to place on my opinion.

Very truly yours

CONCORD SCIENTIFIC CORPORATION

R.B. Caton

ROBERT B. CATON, Ph.D.
Director Toxic Substances

RBC:ms
Enclosures

Construction Safety Association of Ontario

74 Victoria Street, Toronto, Ontario M5C 2A5 • (416) 366-1501

November 29, 1982.

Dr. Fraser Mustard,
Chairman,
Advisory Council on Occupational
Health and Occupational Safety,
400 University Avenue,
Toronto, Ontario.
M7A 1T7

Dear Dr. Mustard:

Thank you for the extension of time for the Council of Safety Associations submission concerning your Discussion Paper on "The Control of Workplace Carcinogens".

Questions on the attached submission should be directed to the Health and Hygiene Standing Committee of the Council of Safety Associations of Ontario so that answers acceptable to each Association can be developed.

Yours sincerely,

Bob Litster

R. (Bob) Litster,
Chairman,
COSA Health and Hygiene
Standing Committee.

RL:blh
attch.

cc: Mr. J. Nugent,
Chairman,
Council of Safety Associations

Mr. L. Sylvester,
Vice-Chairman,
Council of Safety Associations

Council of Safety Associations

November, 1982

INTRODUCTION

The Council of Safety Associations welcomes the opportunity to comment on the Advisory Council's proposals regarding workplace carcinogens. The insidious nature of cancer as a disease together with the complexity of its causes, treatment and prevention make this an urgent subject for consideration.

The Council of Safety Associations represents Associations whose primary mandate is providing education to prevent occupational illnesses and injuries. It therefore takes significant interest in developing approaches to control workplace carcinogens. In carrying out their mandate, the safety associations are particularly aware of the need for clear and technically accurate information about occupational hazards. The provision of such information is an essential starting point for the development of effective control. This aspect received particular attention in this response.

The Council of Safety Associations will be referred to as COSA for the purpose of this report to avoid confusion with Advisory Council and other Councils referred to in this submission.

COSA is grateful for the help provided by a group of recognized experts drawn from industry in preparing this response. Their combined experience, knowledge and information have been invaluable to the Council.

Although the Advisory Council has specifically asked for responses to "Discussion Issues" in its Report, COSA has also addressed the approach and underlying concepts from which those issues are derived. Our response is therefore divided into three parts:—

1. General observations on the Report

2. Considerations in developing an approach to control workplace carcinogens

3. Comments on specific issues raised in the Report under the heading "Discussion Issues".

1. GENERAL OBSERVATIONS

Perspectives: Applying rigid control procedures to carcinogen exposure in the workplace must be weighed against a number of factors, including socio-economic:

- The significant difference between workplace exposure and environmental and lifestyle exposure; COSA is impressed by the survey of scientific evidence presented in the Submission made by J. Weglo and A. Cecutti which strongly suggests that only a small portion of the total exposure is related to the workplace. This is not, of course, to suggest that workplace exposure should not be controlled but, as Dr. Ham says in his submission to the Select Committee on Ontario Hydro:

- "All I plead with us is that when we say "okay, we want this standard to be tougher or that one looser", *we address that question not as an isolated question but in the context of the whole pattern of risks that surround a person working and living in our society*".

- The significance of smoking not only on the incidence of cancer generally but in its synergistic effects with workplace exposures to carcinogens provides an important example of this point.

- The existence of other occupational health hazards in a particular workplace may be of far greater seriousness than carcinogens in that workplace. Death from such other causes is no less final than death from lung cancer. If strict regulations are applied in isolated fashion for occupational exposures to carcinogens, then there is a danger that it will have unwarranted priority over other harmful exposures even in those workplaces where exposure to carcinogens is insignificant by comparison.

- The adequacy of existing scientific information. Strict controls can only be assured of success where they relate to a defined and identified problem. There was only implied definition of carcinogen in the Discussion Paper and the Report of the Special Advisory Committee.

Identification and Control:
In any problem-solving process, there are two distinct steps — first, the clear identification of the problem, its nature, scope and implications; second the development of solutions. The Advisory Council have attempted to deal with both these aspects together in setting out one approach to identification and control. However, a fundamental difficulty occurs. A clear distinction needs to be drawn between the process of fact collection and the ways in which governments react to those facts.

The suggested approach to classification and criteria for testing leave room for political and subjective bias. An example of this is the suggestion that there be public interest representation on the proposed Advisory Committee where doubt on the part of any member of that committee could result in a change of classification.

It is important in the collection and dissemination of factual information to governments and the public that every effort be made to ensure the absence of political, emotional or economic bias.

Once information has been collected, analysed and assessed on scientific grounds and the results made public to government and society, the process of control measures can be considered in an informed manner. Clearly, it is at this stage that political, social and economic criteria must be weighed, and input obtained from all public interest groups.

Cost/Benefit Impact:
The approaches suggested in the Report cannot be considered in isolation from cost/benefit analyses. Without such analyses, the feasibility of the proposals cannot be realistically assessed. We realize that such studies are notoriously difficult; however, attempts can be made to cost out the proposals regarding classification, testing requirements, control measures and the effect on the construction of new plants. On the benefit side, facts such as the number of potentially exposed workers, the incidence of workplace related exposure and so on can be assessed. If the cost of these approaches is not acceptable to government, industry or the taxpayer, then the danger is that new plants will not be built nor new processes developed and industrial initiatives stifled.

Classification System:
COSA is concerned with the classification system proposed, particularly as the classification system is directly linked to the control approach suggested. We believe that this approach is not feasible for the following reasons:—

- It is applying a rigid, simplistic approach in an area where significant uncertainties exist at the present time.

- It relies heavily on in vitro testing despite the fact that there is scientific doubt about the validity of such tests. The Report of the Special Advisory Committee on Carcinogens indicated that short term tests in particular ". . . have only been developed very recently and new ones are still appearing. Their strengths and weaknesses are still not fully appreciated, and practical experience with them is still quite limited."

- It allows for unsubstantiated opinion to influence decisions which may lead to costly and rigid procedures. In effect, the proposal suggested allows for all chemicals which are not proven carcinogens to be classified as suspected carcinogens.

- We question whether there is the jurisdictional authority in Ontario to require off-shore manufacturers of chemicals to undertake testing procedures.

National/International Aspects:
The Report suggests that representations be made to the Federal Government to take initiatives in the collection of data. However, it would appear that strong emphasis is placed on the role of the Provincial Government of Ontario in classification, testing and control programs. We believe that it is unrealistic to expect the Provincial Government to undertake a task of this magnitude, which is of relevance to all Canadian workers. Further, many of the manufacturers, or even importers of products used in the Province lie outside provincial boundaries and jurisdiction. We believe therefore that it is absolutely essential that the task of information collection, analysis and dissemination be done on a co-ordinated national basis. Such role could be undertaken by the Canadian Centre for Occupational Health and Safety, The Science Council of Canada or perhaps, the Federal Government itself. The Canadian Centre, The Science Council or the Canadian Standards Association might then develop guidelines for occupational control procedures, leaving it up to the provinces themselves to decide specifically how to regulate this issue.

Further, COSA must comment on the apparent lack of consideration in the Report for the need for international liaison. We would refer to the "Lesson" on Page 151 of the accompanying report of the Special Advisory Committee on Carcinogens:

"This is an example of the failure of industry in one country to take into account evidence developed in another country."

We live in an era where science and technology are becoming international in scope — this is evident in the advanced information technology. It would be absurd to consider Ontario as becoming the world leader in chemical screening and testing — economics alone would rule out that possibility. It is important therefore that any system established for the screening and assessment of information on carcinogens be established in close co-operation with international agencies such as the International Agency for Research on Cancer, of which Canada is a member. The role which Canada could play in contributing to the general body of knowledge on cancer causing agents in the workplace could relate to those substances about which little is known and which are of particular concern at Canadian workplaces.

2. CONSIDERATIONS IN DEVELOPING AN APPROACH TO CONTROL WORKPLACE CARCINOGENS

We note that the Advisory Council (Dr. Mustard's letter of June 30th) makes it clear that they would welcome comments on issues not covered by the Report. So far in its response, COSA has commented on general concepts and approaches suggested in the Report. In general, COSA is of the view that the proposed approaches to identification, classification and regulation are questionable. However, this does not imply that any approach is impossible or indeed that nothing should be done. For this reason, COSA sets out what is believed to be important considerations in developing alternative approaches:

Information collection and dissemination:
As a first step, all available scientific information relevant to occupational exposure to carcinogens should be collected, analysed and disseminated to all interested parties including governments, employers, workers and trade unions, and professional associations.

The information must be provided ultimately in a form readily understandable by non-experts. It should include information about lifestyle and environmental factors having an influence on the incidence of occupational cancer. It should be collected, analysed and disseminated by a national body having suitable relationships with international agencies.

Risk assessment, acceptable risk and control measures:
A clear distinction should be made in the process of hazard identification and associated risk assessment on the one hand, and the process of determining acceptable risk and control measures on the other.

The first process should be the responsibility of the scientific community under the co-ordination of a suitable agency and should be free from any political influence.

The second process should involve consideration of social, political and economic factors and thus should involve input from appropriate interest groups.

Testing procedures:
Regulated testing and screening procedures should take full account of the developmental stage of such testing procedures. Further, they should take account of cost, feasibility, international evidence already available and priorities for Canadian workplaces.

Advisory Committee:
The Advisory Committee established for the purpose of identification and classification should be composed of the scientific community only. They could develop a list of hazardous substances (not just carcinogens).

The Committee could be chosen from professional/technical experts who are regularly practicing industrial medicine and/or hygiene and have involvement in occupational illness programs. Regular updating of the bank of knowledge developed by the Committee could take place in a similar manner to the ACGIH Committee. This method would be an application of the internal responsibility system which the Government of Ontario supports, and also recognizes the lesson of learning from methods in other countries.

3. COMMENTS ON "DISCUSSION ISSUES"

Issue 1: It is not clear as to what would constitute "Provincial Initiatives" in relation to a National Program. There should be co-ordination of provincial activities in this area through a National agency.

We have already stated that it is critical to ensure close liaison with international agencies.

Issue 2: The question of the proposed Advisory Committee would depend on its role. We have suggested earlier that a clear distinction be made between hazard identification (including risk assessment and classification) and control procedures. Therefore it would be inappropriate in our view for the proposed Advisory Committee to serve both functions.

Issues 3 & 4: We question the feasibility and practicability of this being done on a provincial basis.

Issue 5: Where existing procedures are shown to be inadequate, the testing program(s) should be co-ordinated on a national basis to ensure overall consistency for all Canadian workers. In doing so, the procedure and program decided upon should be based on the best validated scientific evidence.

Issue 6: We disagree with the criteria for classification for the reasons already discussed.

Issue 7: We do not agree with the concept of zero exposure except where there is strong scientific evidence to support this on a case by case basis. Further, such a concept may be unworkable from a socio-economic viewpoint. The ALARA (As Low As Reasonably Achievable) concept would seem to be more appropriate.

Issue 8: We question the reality and practicability of implementing a priority testing program within five years for the Province of Ontario alone.

Issue 9: These questions could all be considered in detail over a period of time by an Advisory Committee formed as suggested in this submission. Response by COSA without more time to reflect on the questions, some of which should be clarified, is not appropriate. At this time all answers would be qualified yes or no answers.

Issue 10: The question of providing resources in order to guarantee the continuance of the Ontario Cancer Registry would seem to be an urgent priority.

Issue 11: On the issue of information, we cannot but agree with the importance of this. However, it must be done in a way to facilitate understanding by non-technical people in the workplace. Further, in accordance with the concept of internal responsibility, information disclosure within a workplace to managers and workers should be the responsibility of employers.

On the question of labelling, this should not be done in isolation from efforts already underway by the Canadian Standards Association to develop a labelling standard for toxic substances in the workplace.

Issue 12: The question of whether or not present penalties under the Act are adequate is a separate question and should not be considered in isolation from the whole question of enforcement of the Act.

Issue 13: We do not believe that workers exposed to carcinogens in research establishments have any greater immunity to cancer than other workers. Therefore, special control procedures appropriate to research establishments and equivalent in end result to those required for industry, should apply.

DOW CHEMICAL CANADA INC.
Modeland Road, P.O. Box 1012, Sarnia, Ontario, N7T 7K7

November 1, 1982

Dr. J. Fraser Mustard
Chairman
Advisory Council on Occupational
Health and Occupational Safety
Ministry of Labour
15th Floor, 400 University Avenue
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

We appreciate the opportunity to comment on the development of a Carcinogen Policy for Ontario and offer the attached brief for the consideration of the Advisory Council.

The Council has done an excellent job of identifying the many difficult issues that must be confronted in formulating a comprehensive carcinogen policy. We have addressed the issues raised by the Council with as much specificity as possible, and have attempted to make positive suggestions when we disagree with an approach suggested in the Discussion Paper.

The Dow Chemical Company has long been involved in the toxicological testing, risk assessment and workplace evaluation and control of carcinogens. We have drawn together this accumulated experience in the first three sections of this brief in the hope that it may be of value to the Council and the Special Advisory Committee on Carcinogens.

We have requested an opportunity for oral dialogue and look forward to continued cooperation with the Council.

Yours truly,

J.M. Lanham M.D.

J.M. Lanham, M.D.
Corporate Medical Director

Dow Chemical Canada Inc.

November, 1982

TABLE OF CONTENTS

	Page
Executive Summary	132
Introduction	135
Testing Methods for Carcinogenicity	137
Carcinogenic Risk Assessment	150
Monitoring and Control of Chemical Exposure in the Workplace	165
Comments on the Discussion Paper "The Control of Workplace Carcinogens"	170
Comments on "Issues for Consideration"	175
References	188
Glossary of Abbreviations	194
Appendix: "Quantitative Risk Assessment: State-of-the-Art for Carcinogenesis" by Colin N. Park and Ronald D. Snee	195

EXECUTIVE SUMMARY

TESTING FOR CARCINOGENICITY

Testing methods should be flexible and allow for sound scientific judgment. A flexible testing scheme can benefit from the latest advances in the developing science of toxicology.

Testing methods should be concordant with existing provincial, national and international testing programs for chemicals. Unilateral action by Ontario would result in:

- Unnecessary and expensive duplication
- Non-tariff barriers
- Damage to Ontario industry's competitiveness

Testing requirements should be practical and cost-effective.

> The most cost-effective approach is a sequential tier testing scheme with one or more tests at each tier. Such a system based on one used by Dow toxicologists is proposed (Fig.1).

Advantages of a three-tier system over the two-tier system suggested in the Council's Discussion Paper include:

- Greater cost-effectiveness;
- Does not overburden expensive animal testing facilities with many chemicals likely to be non-carcinogenic;
- Tier 2 tests more definitively select chemicals for long-term animal testing;
- Going directly from Tier 1 to Tier 3 involves waiting 3 - 5 years to find out whether a positive Tier 1 result is real or false;
- International acceptability.

CARCINOGENIC RISK ASSESSMENT

Understanding the mechanisms of carcinogenesis is critical in assessing the risk of a substance to man. Two broad classes of carcinogens are now widely recognized:

Genotoxic agents:

- Initiators;
- Act directly on the genetic material of human cells;
- Protective effects of bodily defence mechanisms give rise to "practical threshold" levels at low doses;
- Vinyl chloride is a well studied example.

Non-genotoxic (epigenetic) agents:

- Promoters or modifiers;
- Induce or enhance tumor development by non-genetic mechanisms;
- Threshold levels established.

There is general scientific and government recognition of carcinogenic thresholds.

A realistic risk assessment model is proposed, taking into account:

- Mathematical extrapolation models;
- Carcinogenic mechanism;
- Animal-to-man factor
- Dose-response relationship.

In Estimating Human Risk from animal tests, key considerations are:

- Estimation of workplace exposure;
- Extrapolation from high to low dose;
- Extrapolation from test animals to man.

MONITORING AND CONTROL OF CHEMICAL EXPOSURE IN THE WORKPLACE

Risk presented by a substance depends on:

- Its inherent toxicity and
- The extent of likely human exposure.

Exposure is the only variable we can control, through:

- Engineering controls;
- Administrative controls;
- Personal protective equipment;
- Employee education and training.

Monitoring establishes exposure levels, provides early warning of leaks and measures effectiveness of control measures.

- Personal monitoring (worker's breathing zone);
- Area monitoring (various workplace locations).

COMMENTS ON THE DISCUSSION PAPER: "THE CONTROL OF WORKPLACE CARCINOGENS"

- Chemical carcinogens cannot be dealt with generically because they act via different mechanisms and exhibit a million-fold range of potency;

- Categorization of carcinogens is neither practical nor necessary. We recommend a case-by-case approach in conjunction with a 3-tier testing scheme;

- The critical issue is not just the carcinogenicity of a substance but worker safety. This depends on both the carcinogenic potency and the potential level of human exposure in the workplace;

- Too little emphasis is placed on the importance of measuring and controlling worker exposure;

- The "one tonne rule" is an administrative convenience, not a reliable measure of workplace exposure. There is no simple relationship between production volume and potential for worker exposure.

COMMENTS ON "ISSUES FOR CONSIDERATION"

- We question giving precedence to cancer over other serious workplace health hazards;

- An advisory committee, made up of scientists from academia, government, industry and labor, should deal only with scientific matters;

- Chemical structure and relationship to known carcinogens should be only one of many factors considered in examining new chemicals;

- Decision as to the suitability of substitutes for carcinogens depends on a large number of factors. Chemical manufacturers are in a better position to balance these factors than regulators;

- Potential substitutes should be subjected to the same rigorous health and safety scrutiny as the carcinogens which they are to replace;

- Permissible exposure limits should be based on no-observed-effect levels, rather than on analytical detection levels;

- Workers should enjoy the same degree of health protection and surveillance, whether they work in old or new plants;

- A balance must be struck between the workers' legitimate right to know about workplace hazards and the company's legitimate right to protection of its trade secrets.

INTRODUCTION

Worldwide efforts to regulate carcinogenic substances did not begin in earnest until about 1970. Although many questions remain about the biological process of tumor development, a substantial amount has been learned since then about assessing and managing the risks associated with carcinogenic substances.

In 1970 there was no valid basis for assessing the scope of the problem of occupationally related cancer; epidemiologists now have a much better grasp of the problem. Occupational exposure to chemical carcinogens appears to make a relatively minor contribution [2-8% (1)] to the overall human cancer burden but, as Doll and Peto (2) have noted:

> "Occupational cancer....tends to be concentrated among relatively small groups of people among whom the risk....may be quite large, and such risks can usually be reduced, or even eliminated, once they have been identified. The detection of occupational hazards should therefore have a higher priority in any program of cancer prevention than their proportional importance might suggest."

Since 1970, toxicologists have expanded and refined their understanding of carcinogens and have developed new tests which are extremely useful in evaluating the potential carcinogenicity of chemicals. Some examples of advances in this area include new short-term mutagenicity tests, better appreciation of the value of pharmacokinetic data, better understanding of dose-response relationships, and a realization of the difference between genotoxic and non-genotoxic mechanisms of carcinogenesis. The availability of more sophisticated and diverse data has rendered obsolete the heavy reliance on mathematical extrapolation models applied to long-term animal bioassays.

These scientific advances reveal the complexity of the factors inherent in assessing the risk of carcinogenic chemicals. Moreover, the day-to-day experience of regulatory officials has made clear the need for flexibility in carcinogen policy. Thus, a generic approach to carcinogen regulation has been generally abandoned, because the complex issues involved in risk management do not allow meaningful classification of chemicals into broad categories. The same considerations dictate the need for testing requirements to be flexible.

In the past decade, industry and labor have significantly reduced workplace exposure to carcinogens through effective employer and union hazard communication programs, engineering controls, extensive monitoring and improved health surveillance programs.

Finally, much thought has been given to the philosophical and theoretical basis of risk assessment. Many writers have stressed the social desirability of weighing the benefits of a chemical against the risk it poses, and the need for cost-effective regulations. Since the everyday world is full of risks of the same magnitude as the carcinogenic risk of chemicals, careful allocation of available resources is needed to reduce involuntary risks generally.

In this submission we have presented our views on some of the more significant features of the current scientific position on the regulation of potentially carcinogenic chemicals. We strongly urge the Advisory Council to beware of locking itself into regulatory strategies which are not defensible in the light of current scientific developments.

TESTING METHODS FOR CARCINOGENICITY

I. TESTING REQUIREMENTS SHOULD BE FLEXIBLE AND ALLOW FOR SOUND SCIENTIFIC JUDGMENT.

Toxicology is a developing science, continually receiving fresh inputs from new developments in many other medical and natural sciences. Concerned with harmful effects of poisons on living organisms, toxicology uses biological systems as the subjects of research and testing. Biological systems exposed to chemical substances exhibit wide variations in type and degree of response between individuals and species.

Because of the limitations of toxicological tests and the difficulties in extrapolating their results to man, any testing scheme adopted should leave room for sound scientific judgment at every stage of testing. Testing requirements must be flexible enough to allow incorporation of the latest advances in toxicological science and methodology.

II. TESTING REQUIREMENTS SHOULD BE CONCORDANT WITH EXISTING PROVINCIAL, NATIONAL AND INTERNATIONAL TESTING PROGRAMS FOR CHEMICALS.

The development of the carcinogen policy for Ontario should be viewed against the backdrop of international activity. Harmonization of testing requirements and mutual acceptance of data are essential to avoid overloading testing facilities. A "made in Ontario" carcinogen policy which failed to recognize these national and international realities would create conflicts with other jurisdictions, resulting in:

- Unnecessary and expensive duplication;
- Non-tariff trade barriers;
- Adverse effects on innovation and competitiveness of Ontario's manufacturing sector, caused by unavailability of new chemicals.

The following existing testing programs are relevant:

1. United States Toxic Substances Control Act (TSCA) Section 5 - Premanufacturing Notification. Assessment of the potential risks of all new chemicals prior to manufacture is required, but there is no prescribed set of mandatory testing requirements.

2. European Economic Communities (EEC) 6th Amendment - Regulates the testing of new substances for environmental exposure and toxicity. A base set of test requirements is prescribed for new chemicals. Further studies at a later stage are arranged in a step system.

3. Organization for Economic Cooperation and Development (OECD) international approach to the testing of chemicals (proposed to be adopted by Canada in the near future)—

   a) Methods (Guidelines) for conducting various human health and environmental effects tests;

   b) Good Laboratory Practice (GLP) principles governing the management and operation of testing laboratories; laboratories;

   c) Test data generated in one OECD member country would be accepted by the regulatory authorities of other OECD countries;

   d) Sequential tier testing schemes for assessing the safety of new chemicals starting with the minimum premarket data requirements (MPD).

4. Occupational Health and Safety Act of Ontario (Bill 70) - Premanufacture notification. Guidelines for submission of "notice of intent to manufacture, distribute or supply a new chemical agent or a combination of such agents."

The 3-tier testing scheme used by The Dow Chemical Company to assess the toxicological properties of new chemicals is shown in Table I. Similar 3-tier schemes have been proposed by OECD and adopted by EEC (3). The number and types of studies to be done on a chemical are selected based on the number of people exposed, inherent toxicity, potential level of exposure, nature of the chemical (e.g. persistent, cumulative) and the amount of the chemical produced. Carcinogenicity is one of many toxicological effects considered in such total assessment schemes.

TABLE I

DOW'S TOXICOLOGY TESTING SCHEME FOR NEW CHEMICALS

TIER 1

Acute Toxicity

Oral Lethality (Rats)

Dermal Lethality (Rabbits)

Inhalation Lethality (Rats)*
or 4-hour saturated vapor test*

Eye Irritation (Rabbits)

Skin Irritation (Rabbits)

Skin Sensitization †

Initial Screening Tests
for mutagenic/carcinogenic potential

TIER 2

Subacute Toxicity

14 to 30-day Oral or Inhalation (Rats)

Screening Tests for mutagenic/carcinogenic potential of chemicals

TIER 3

Subchronic Toxicity - 90-day, two species

Reproduction Test

Teratology - two species

Pharmacokinetics and Metabolism Study

Chronic Toxicity + Carcinogenicity Study

---

* If there is significant exposure to gas or vapor.

† If test compound is structurally similar to known skin sensitizers.

III. TESTING REQUIREMENTS SHOULD BE PRACTICAL AND COST-EFFECTIVE

It is customary to conduct carcinogenicity bioassays on individual chemicals, although some work is done on technical grade material rather than the pure substance. If tests were done on mixtures of chemicals, the results would only be valid for that particular composition. Because of the prohibitive cost and the limited number of specialized testing facilities and highly trained professionals, it is not practical to conduct bioassays on all chemicals, mixtures and end-products (usually formulated mixtures).

A company introducing a new chemical must consider the cost of toxicological testing in the light of that chemical's expected earnings over its anticipated commercial life. Clearly, if the expense of a rigidly prescribed battery of tests exceeds the new chemical's anticipated cumulative profitability, the company has no alternative but to abandon what might have become a socially valuable product. A flexible testing scheme allowing a limited number of tests, selected and interpreted with enlightened professional judgment, would release such valuable, low-volume products for public use. Later, when such a product becomes more widely accepted and more people have potential for exposure to it, further testing may be appropriate. Wider potential use justifies further testing in anticipation of higher potential earnings.

IV. TIER TESTING FOR MUTAGENIC/CARCINOGENIC POTENTIAL

The most cost-effective approach toward testing for carcinogenicity of chemicals is a sequential tier testing system with one or more tests at each tier. A three-tier testing system based on that currently used by Dow toxicologists is shown in Figure 1. The individual tests are listed in Table II, together with the approximate costs.

TIER 1: INITIAL SCREENING TESTS FOR MUTAGENIC/CARCINOGENIC POTENTIAL

Short-term *in vitro* screening tests offer a rapid and inexpensive method for predicting mutagenic or carcinogenic potential. There is considerable lack of agreement as to which specific tests should be conducted for specific chemicals, but scientists agree that no single test by itself reliably predicts potential mutagenicity or carcinogenicity. The most acceptable approach is to perform a battery of tests. Which tests to include in each tier should be based on good scientific judgment but costs must also be considered.

It should be emphasized that the purpose of the Tier 1 tests is not to define what is a mutagen or carcinogen, but to select those substances which should be given priority for the more extensive Tier 2 tests.

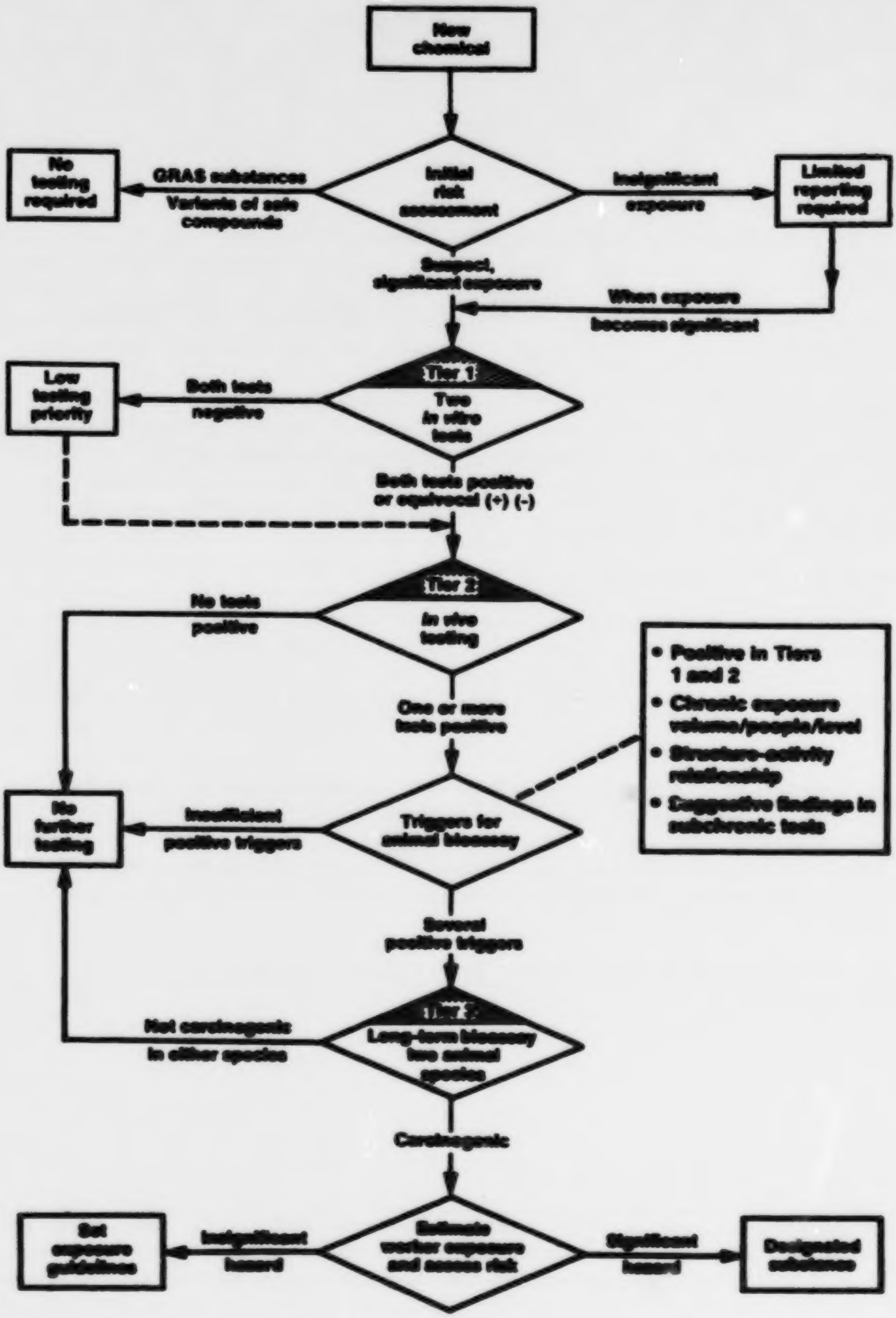
New chemical
Initial risk assessment
GRAS substances
Variants of safe compounds
No testing required
Insignificant exposure
Limited reporting required
Suspect, significant exposure
When exposure becomes significant
Tier 1
Two in vitro tests
Both tests negative
Low testing priority
Both tests positive or equivocal (+) (-)
Tier 2
In vivo testing
No tests positive
One or more tests positive
Triggers for animal bioassay
Insufficient positive triggers
No further testing
• Positive in Tiers 1 and 2
• Chronic exposure volume/people/level
• Structure-activity relationship
• Suggestive findings in subchronic tests
Several positive triggers
Tier 3
Long-term bioassay two animal species
Not carcinogenic in either species
Carcinogenic
Estimate worker exposure and assess risk
Insignificant hazard
Set exposure guidelines
Significant hazard
Designated substance

Figure 1   Dow's Proposed Carcinogen Tier Testing Scheme

TABLE II

A TIER TESTING SYSTEM FOR IDENTIFYING CARCINOGENS

TIER 1	
Initial Screening Tests For Mutagenic/Carcinogenic Potential	**$7,000**
Salmonella typhimurium **tester strains (Ames test) with and without metabolic activation**	
Unscheduled DNA synthesis in rat hepatocytes	
TIER 2	
Screening Tests For Mutagenic/Carcinogenic Potential	**$50,000 per test**
In vivo **cytogenetics (rats)**	
Dominant lethal test (rats or mice)	
Micronucleus test	
TIER 3	
Long-Term Carcinogenicity Studies In Laboratory Animals (Two Species)	**$800,000 to $1,100,000**

In the first tier we recommend microbial tests, specifically the *Salmonella* organisms (Ames test) with and without metabolic activation, and the test for unscheduled DNA synthesis in rat hepatocytes. Additional tests could include those using Chinese hamster ovary (CHO) mammalian cell *in vitro*.

The purpose of the first level screen for mutagenic potential is to rapidly identify those chemicals which are genetically active and therefore should be given a higher priority for further testing. In the most widely used first tier screen, microbial test (Ames test), any quantitative estimate of mutagenicity may only be relevant to the artificially constructed strains of bacteria* used and may not correlate with the relative activity of this chemical in higher organisms (animals and humans) or even in other micro-organisms. Despite various correlations between positive Ames tests and mutagens or carcinogens, many false positive and false negative results have been reported. The predictive power of the Ames test for mutagenicity or carcinogenicity is poor and depends on the class of chemicals being tested.

No decisions on the safety of substances can be made from results at this first tier of testing. Negative findings in both the first tier screening tests indicate a lower probability of mutagenic or carcinogenic potential, positive findings in both the first tier tests would give the chemical a higher priority for further testing (Tier 2).

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* The Ames test is a back-mutation assay. The *Salmonella* strains of bacteria used have been mutated to require histidine for growth, to impair or cause a lack of DNA repair enzymes and to possess impaired (leaky) cell walls.

TIER 2: SCREENING TESTS FOR MUTAGENIC/CARCINOGENIC POTENTIAL

These additional tests serve to affirm or refute the mutagenicity of a chemical using higher test organisms and thus more precisely define the types of mutagenic events induced. For the second tier we recommend one or more of the following tests:

- *In vivo* cytogenetics*;
- Dominant lethal or modified dominant lethal test†;
- Micronucleus test.

If a substance is positive in the Tier 1 screening tests but negative in Tier 2, the initial positive result is presumed to be peculiar to the microbial or *in vitro* cellular test system used and has questionable application to mutagenicity or carcinogenicity in higher test systems (animals and humans). If, however, a substance positive in Tier 1 is also positive in Tier 2, it may pose a mutagenic hazard and precautions should be taken to control human exposure. Furthermore, the substance should be given a high priority for Tier 3 long-term carcinogenicity testing.

TIER 3: LONG-TERM CARCINOGENICITY STUDIES IN LABORATORY ANIMALS

Chronic or long-term studies are conducted in two species of rodents (mice, rats, hamsters) to assess the toxic potential, specifically the carcinogenic potential, associated with long-term exposure. If Tier 3 animal tests are negative and Tier 1 & 2 screening tests are positive, the substance is assumed to be non-carcinogenic.

---

* The cytogenetic test shows greatest sensitivity with acute or subacute exposure to dose levels higher than normally used in subchronic or chronic studies.

† We have conducted the dominant lethal test using the old protocol as well as the modified protocol wherein dosage of the male rats continues for a period of approximately 70 days followed by two (2) one-week periods of mating with different unexposed females. Both protocols provide useful information.

1. Judicious Choice of Substances for Carcinogenicity Bioassay

These chronic toxicity carcinogenicity studies involve hundreds of animals and require from three to five years to conduct. To test one chemical in two animal species, e.g. rats and mice, would cost $800,000 to $1,100,000 today. Obviously, there is not sufficient space, staff, money or time to conduct these animal bioassays for all new or existing chemicals, hence the need for judicious choice of substances.

A chronic animal bioassay is needed for a chemical if several of the following considerations or "triggers" are positive:

TRIGGERS FOR ANIMAL BIOASSAY

- Positive in Tier 1 and Tier 2
    mutagenicity/carcinogenicity tests
- Chronic exposure
    Large volume of production
    Many people exposed
    High level of repeated exposure
- Structure-Activity Relationship
    Structure closely related to known carcinogen
- Suggestive findings in subchronic tests
- Suggestive findings in epidemiological studies (old chemicals)

Several
positive
triggers
needed

Human exposure conditions are important factors. For example, if a chemical is made and consumed in a reactor and human exposure could only happen through an accidental spill or rupture of a vessel, there is no need for expensive chronic toxicity studies involving repeated exposures over long periods of time. In contrast, chemicals to which workers might be exposed throughout their working lifetime should be examined for chronic toxicity including oncogenic potential.

2. Animal Versus Human Carcinogens

Properly designed and conducted animal bioassays provide direct evidence of carcinogenicity in animals. Chemicals that cause tumors in animals may or may not cause tumors in humans, but they should be treated as potential human carcinogens. Verification that the agent is a human carcinogen requires properly designed and conducted human epidemiological studies. The International Agency for Research on Cancer (IARC) stated in 1979 that convincing evidence for human carcinogenicity was available for only 18 substances. It listed 142 substances for which data are sufficient to conclude that they are carcinogenic in animals. When a substance has been shown with sufficient evidence to be an animal carcinogen, increased care must be taken to reduce human exposure potential and health surveillance programs including epidemiological studies should be carried out, if practical.

3. Properly Designed, Conducted and Evaluated Carcinogenicity Tests

Despite the apparent simplicity of the bioassay procedures, it is rather difficult to properly design, execute and evaluate a carcinogenicity study. The scientific literature is replete with examples of poorly-designed and conducted studies which have led to misleading and conflicting results.

Protocol guidelines have been published by a number of agencies.* The choice of which protocol to follow should be flexible, bearing in mind the need to avoid conflict with the requirements of other jurisdictions, but it is essential that the key features detailed in the section VI be included.

V. WHY HAVE A 3-TIER TESTING SCHEME? THE ONTARIO CARCINOGEN POLICY TASK FORCE HAS RECOMMENDED A 2-TIER TESTING SCHEME.

1. The tier 1 *in vitro* tests are designed for rapid and inexpensive initial screening of a chemical's ability to interact with DNA in artificially constructed strains of bacteria or in isolated single cell system. These tests do not indicate mutagenicity in whole animals or humans since intact animals would have detoxification and elimination mechanisms, DNA repair systems and selective absorption and distribution mechanisms in operation. All these systems are absent in the Ames test bacteria.

---

* Protocols have been issued by OECD and WHO, in the United States by NCI, FIFRA and TSCA, and in Canada by Health and Welfare.

2. The Ames test has been shown to be positive in cooked foods such as meat and fish, and in coffee, tea, sugar and many chemicals common to our current lifestyle. Because of the significant probability of Ames test false positives, it would not be cost-effective to go directly from the Tier 1 tests to long-term animal carcinogenicity testing. It would be wasteful of resources and time to overburden Tier 3 with a vast number of chemicals which have a high probability of being non-carcinogenic.

3. Tier 2 tests are more definitive tests for mutagenicity. Since mutation is hypothesized to be the initiation event in carcinogenesis, Tier 2 tests would therefore better define and select chemicals for carcinogenicity testing. This would make the carcinogenicity testing more cost-effective.

4. The time factor is particularly critical. Going directly from Tier 1 to Tier 3 means a three to five-year regulatory vacuum while we wait to find out whether a Tier 1 positive chemical is a carcinogen or a false positive. Tier 2 tests would quickly eliminate false positives.

5. The 3-tier testing scheme proposed here is generally accepted and used by a number of chemical companies and other regulatory bodies such as OECD and the EEC countries in assessing the toxicological properties of new chemicals.

VI. LONG-TERM CARCINOGENICITY STUDIES: METHODOLOGY

1. General Considerations

a. Carcinogenicity tests are generally conducted in rats or mice because they are small and easy to handle, have a relatively short life span, are available in large numbers in inbred and hybrid strains that have predictable background or spontaneous tumor rates.

b. Treatment should be continued over the greater portion of the animals' life span.

c. Carcinogenicity tests should employ appropriate numbers of animals, current protocols generally calling for 50 animals in each group.

Larger groups would be impractical because of the logistical problems of managing the animals and maintaining adequate records, the limited statistical advantage from further increases in group size, and limited testing resources.

d. Because spontaneous tumors are observed in all animal species, appropriate concurrent control groups should be used. The interpretation of every cancer study rests primarily upon comparing the spontaneous or background rate of tumor occurrence in the untreated controls with the rates observed in the treated animals.

2. Proper Selection of Dose Levels

a. Multiple dose levels should be used. To maximize the chance of detecting any carcinogenic effect, the highest dose tested should be a maximum tolerated dose which produces some toxic or physiologic response but it should not saturate the normal metabolic and detoxifying mechanisms operating in the animals, nor shorten their lifespan. The lower dose levels are useful in assessing any dose-response relationship.

b. Well-designed subchronic toxicity and metabolism/pharmacokinetics studies should be carried out and results from these experiments used to ensure proper selection of dose levels of the test substance for the long-term carcinogenicity studies. This has now been generally accepted and required in the more recent carcinogenicity procedure guidelines published by OECD (4) and TSCA (5). The high dose selected as the maximum tolerated dose ordinarily should not saturate the normal metabolic and detoxifying mechanisms operating in the animals. If it does, extrapolation of the results obtained from the high dose to the low dose situation would be inappropriate.

c. There is now general recognition of the limited value of earlier carcinogenicity studies by the National Cancer Institute, in which doses of the test substance were massively larger than humans could possibly be exposed to. Because of massive overt toxicity observed in the treated animals and because the normal detoxifying mechanisms in these animals were saturated, results from these studies cannot be extrapolated from high dose to low dose situations and are of little value in assessing the real carcinogenic risks to humans.

3. Autopsy and Pathology

a. Each animal from both control and treatment groups should be subjected to a thorough autopsy and pathologic examination by a competent animal pathologist, with microscopic examination of sections from all major organs and tissues.

b. Thorough examination by an experienced animal pathologist is particularly important with respect to specific tissues. Because tumors may occur spontaneously in all tissues, a detailed knowledge of spontaneous tumor incidence in the particular strain of animal tissue is necessary.

4. Evaluation of Results

a. Between 35 and 40 tissues are examined for each animal in a carcinogenicity study, resulting in 15,000 to 20,000 tissues examined in one study.

b. False positive statistical results are frequently encountered because these studies require multiple statistical comparisons of data for two sexes, in several dose levels, for many different tissue sites and types of tumors at the .05 significance level.

c. It is essential that both biological plausibility and statistical considerations be used in evaluating the results of carcinogenicity studies.

d. The presence of a dose-response relationship and the reproducibility of results are particularly important in the interpretation of the data.

e. The pathologist should take into consideration the available historical control data from the same laboratory, which may show that a statistical difference is within the expected range of variation and is not biologically significant.

SUMMARY

We recommend a flexible approach to testing, open to new advances in toxicological science and allowing the exercise of sound scientific judgment. A sequential tier testing system is the most scientifically rigorous and cost-effective procedure because it permits the orderly prioritization of substances for long-term animal bioassay. A generally accepted three-tier system is proposed and its advantages over the two-tier system proposed in the Advisory Council's Discussion Paper are outlined. Proper interpretation of short-term mutagenicity test results is critical for judicious choice of substances for animal tests. The criteria for design, execution and evaluation of long-term carcinogenicity bioassays are discussed. Selection of appropriate dose levels is of crucial importance.

CARCINOGENIC RISK ASSESSMENT

I. MECHANISMS OF CARCINOGENESIS AND THE QUESTION OF THRESHOLDS

A. Introduction

Normally, when a substance produces a positive carcinogenic response in laboratory bioassays, we know little, if anything, about the biological mechanism that is producing the response. Yet any safety evaluation of the substance depends critically upon such knowledge.

If the response is caused by an agent such as penetrating ionizing radiation which passes readily through tissues and membranes directly to the genetic material of the cell (DNA), then relatively low doses may produce small but finite increases in cancer.

In contrast to ionizing radiation, chemicals which produce cancer must elude various bodily defence mechanisms (generally inoperative against radiation) before reaching the genetic material of the cell. If a carcinogenic response is produced by a chemical only at high dose levels, where bodily defence mechanisms are overwhelmed, then the chemical may, depending upon the carcinogenic mechanism, pose little or no carcinogenic risk at the subtoxic dose levels encountered in everyday experience.

Cancer research has long distinguished between initiators (genotoxic carcinogens) and promoters or other types of modifying agents (non-genotoxic or epigenetic carcinogens). Since initiators are considered to act directly on the genetic material of the cell, scientists are generally apprehensive about accepting the existence of thresholds for their carcinogenic effects. Because of the protective effect of bodily defence mechanisms, however, the degree of carcinogenic response for initiating agents will almost certainly decline more than proportionately with dose at low dose levels, giving rise to *'practical threshold' levels for genotoxic carcinogens.*

By contrast, promoters or modifying agents induce or enhance a positive carcinogenic response in laboratory animal bioassays by some form or forms of non-genetic mechanism. These non-genetic mechanisms may include one or more of the following:

(1) hyperplastic toxicity, i.e., an increased rate of DNA synthesis and cell replication in response to a toxic insult which, in turn, increases the normal rate of chance mutations or promotes cells already initiated by other agents;

(2) alteration of enzyme activity which controls the production of reactive (carcinogenic) metabolites which, in turn, impair normal excretion or detoxification of chemicals; or

(3) impairment of the body's immune system including excesses or deficiencies of certain micro-nutrients such as vitamins or minerals.

The common feature of all of these phenomena is that there are threshold dose levels, identifiable in laboratory experiments, below which such effects do not occur. Even at dose levels above the threshold, the effects observed are generally reversible if administration of the chemical ceases or if dose levels are reduced below the threshold. Thus, *threshold levels exist for non-genotoxic or epigenetic carcinogens*.

B. Genetic Mechanisms of Carcinogenesis.

Cancer, whether in man or animals, is the result of a complex and variable multistage process leading eventually to the formation of a colony of malignant cells called a malignant neoplasm. The carcinogenic process may be initiated when genetic material of a cell (DNA) is damaged or altered as the result of direct interaction with a physical, chemical or other agent. Agents capable of altering or damaging genetic material (genotoxic agents) may include physical agents (such as ionizing radiation), oncogenic viruses, and both naturally-occurring and man-made chemicals (6).

Damage to genetic material (DNA) within the cell most commonly leads to cell death. Those cells which survive with an altered DNA can be easily and rapidly repaired by natural intracellular repair mechanisms. An altered but unrepaired cell cannot lead to cancer unless cellular division occurs and the cell alteration or mutation is passed on to future cellular generations. This event, known as a mutation, may result at the cellular level only in a rare combination of circumstances where a genotoxic agent does not produce cell death and repair mechanisms within the cell are unable to repair damage to the DNA before cell division occurs.

Even when an initial mutation occurs, however, the cell and its progeny do not attain the malignant state immediately. A number of cell divisions (generations) appear to be needed for a colony of cells to attain the state of relative autonomy characteristic of a malignant neoplasm.

In general, there are bodily defence mechanisms which tend to prevent initiation, subsequent mutation, and ultimate proliferation of cancerous cells. These defence mechanisms operate before, when and after an initiating agent interacts with or damages the DNA.

Before a cell may be initiated, the initiating agent must, of course, reach the DNA of the cell. This need never occur at a level sufficient to cause cancer because the body has a myriad of detoxification and excretion mechanisms which operate essentially as screens to filter out harmful agents long before they can cross the cell and nuclear (nucleus of the cell) membranes. Such excretion and detoxification mechanisms are mediated (controlled) by enzymes within the body. When such mechanisms are overwhelmed by high doses of a chemical carcinogen (as frequently occurs in high-dose animal tests), the linear extrapolation of these toxic or carcinogenic effects to much lower doses is scientifically questionable on biological grounds (7,8).

Even if a chemical penetrates the cell and nuclear membrances and damages DNA, defence mechanisms within the cell operate to repair or destroy aberrant cells before cell replication can take place. Like the detoxification and excretion mechanisms discussed above, these intracellular defence mechanisms appear to be enzyme mediated and thus may be overwhelmed at high doses.

Finally, there is growing evidence that immunologic surveillance mechanisms exist which kill or suppress multiplication of aberrant cells after the initial mutation takes place (9,10,11). This is particularly true for cells initiated by oncogenic viruses endogenously present in the body (4).

From the foregoing discussion, two critical features of the genetic mechanism emerge. First, because carcinogenesis begins at the cellular level when a genotoxic agent alters or damages the DNA, it follows that a chemical (or metabolite of the chemical) must be genotoxic in order for the chemical to be considered an initiator. Whether a chemical is genotoxic, in turn, may be evaluated by testing the chemical's ability to bind covalently with DNA or to produce excess cell mutations in *in vivo* and/or *in vitro* mutagenicity tests.

Second, even in the case of initiators, there are strong reasons to expect a disproportionate decrease in carcinogenic response at low dose levels. Thus, at high dose levels where detoxification, excretion or repair mechanisms have been overwhelmed, the relationship between dose and response may be nearly linear because the number of mutations at the cellular level is likely to be roughly proportional to the chemical dose administered. But at lower doses, where normal defence mechanisms are operative, one would expect a disproportionate decrease in the effective genotoxic dose (the dose actually interacting with DNA) due to the success of the body in screening out the initiating agent before it can damage or alter DNA (7,8). *For these reasons, 'practical threshold' levels exist for genotoxic carcinogens.*

Accordingly, when the evidence indicates that a chemical does not alter or damage DNA or is negative in mutagenicity testing, there appears to be no basis for using a linear, non-threshold model for extrapolating risks to low dose levels. Moreover, even when a substance is demonstrated to be mutagenic, it is unlikely that a linear relationship properly describes the dose-response curve at low dose levels. Rather, at levels below which excretion, detoxification and repair mechanisms are overwhelmed, one would expect a disproportionate decrease in response so that a linear model would substantially overestimate the risk.

C. Vinyl Chloride: a Genotoxic Carcinogen which has a Practical Threshold

Vinyl chloride, a human carcinogen which has been extensively studied, is a good model of a genotoxic carcinogen. The evidence indicating that vinyl chloride has a 'practical threshold' (i.e. a no-observable-effect level) is as follows:

(1) The most recent data of Maltoni indicate a possible increase in angiosarcoma in rats exposed to 10 ppm of vinyl chloride but *no* statistically significant increase in tumors was found in experimental rats exposed below 10 ppm (12).

(2) The metabolic studies have shown that rats are more susceptible than humans to tumor induction by vinyl chloride (13,14) and that human experience should be given higher importance than animal studies. Furthermore it has been demonstrated that vinyl chloride can be metabolically detoxified by reaction with glutathione in the liver.

(3) In assessing the risk of angiosarcoma in workers exposed to vinyl chloride, Gehring *et al.* (14,15) have shown that there is a disproportionate decrease in angiosarcoma at low doses and that the one-hit model greatly overestimates the cancer risk of vinyl chloride workers.

(4) Extensive human experience and epidemiological studies based on forty years' manufacture and use of vinyl chloride should be given precedence over animal studies:

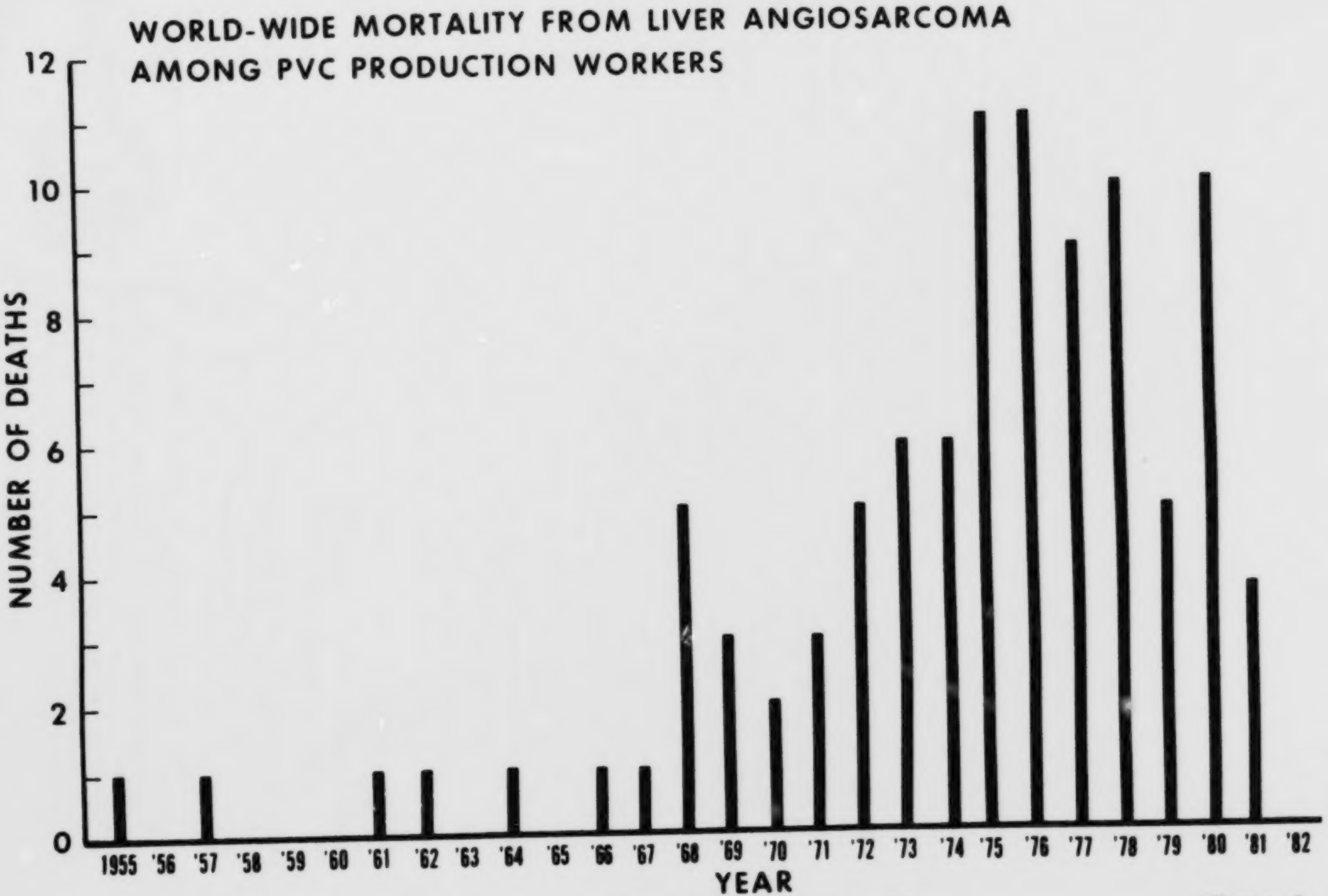
- Angiosarcoma of the liver has been linked with chronic exposure to high (>200 ppm) levels of vinyl chloride in the two major human epidemiological studies (16,17) no angiosarcomas were observed below 200 ppm.

- Groups of workers chronically exposed to levels which were low, but well in excess of 5 ppm, were found to have *no* angiosarcoma (18,19).

- No liver damage or any other vinyl chloride related disease has been observed with a chronic occupational exposure to vinyl chloride of 50 ppm or less (20).

(5) The world-wide mortality statistics from liver angiosarcoma among polyvinyl chloride (PVC) production workers are shown in Figure 2. Despite increased production of vinyl chloride and PVC and the associated increase in the number of exposed workers (to hundreds of thousands), the total world-wide angiosarcoma mortality has declined since 1976. Most of the angiosarcoma cases (97 to date, world-wide) have occurred among kettle cleaners in PVC plants, a group exposed to vinyl chloride levels estimated at thousands of ppm.

The Dow Chemical Company has been engaged in the manufacture of vinyl chloride for 37 years (Dow Canada for 22 years) and no angiosarcoma cases have been reported among its vinyl chloride workers even though exposures prior to 1965 are known to have exceeded a 200 ppm time-weighted average.



WORLD-WIDE MORTALITY FROM LIVER ANGIOSARCOMA AMONG PVC PRODUCTION WORKERS

Based on Data Compiled by Dr. John Stafford, August, 1982.

Figure 2.

D. Non-Genetic Mechanisms of Carcinogenesis

It has long been recognized that substances which are not initiators or are only weakly mutagenic may nonetheless promote or modify the carcinogenic potential of genotoxic agents. The initial experiments of this kind were done by Berenblum, Shubik and others investigating chemically-induced skin cancer in rodents. Such "promotional" phenomena have subsequently been observed however, not only in skin cancer, but in the induction of malignancies in the liver (21,22), fore-stomach (23), lung (24), breast (25), kidney (26) and colon (25,27-30).

Various mechanisms have been implicated in such promotional phenomena but one important mechanism appears to be *hyperplastic toxicity*, meaning the variety of effects seen at the cellular level when an organ or system responds to toxic insults. Thus, when confronted with a toxic insult, the affected organ responds with more rapid cell replication (turnover), increased DNA synthesis, and a variety of changes associated with enzyme and membrane function (6).

Such cellular level effects can promote carcinogenesis either in cells initiated by genotoxic agents endogenously manufactured in the body (such as nitrosamines) or, perhaps even in the absence of an endogenous initiating agent, as the result of an increase in the small but finite error rate that always accompanies DNA synthesis (31). Thus, the normal frequency of chance mutations may be greatly enhanced by an increased rate of DNA synthesis accompanying hyperplastic toxicity. This process may be further accelerated if the DNA repair rate remains constant or is depressed as a result of an enzymatic imbalance created in response to the toxic insult (32,33).

These ideas are supported by Laroye (34) who noted that cancers are more likely to develop in chronically inflamed or scarred tissue (colon cancer in patients with ulcerative colitis or squamous cell carcinomas in ulcers of burn scars). In addition, results from animal tests have been consistent with the role of hyperplastic toxicity in carcinogenesis (35,36), including some done in our own laboratory.

For example, we have developed evidence that perchloroethylene produces hepatocellular carcinomas in mice by non-genetic means (37). To determine whether increased DNA synthesis was occurring in the liver due to toxic liver damage, we injected a normal constituent of DNA (radioactively labelled thymidine) into perchloroethylene-treated animals and controls. By use of this radioactive tracer we determined, following necropsy and histopathological examination, that liver weights had increased and DNA synthesis had doubled over controls, thereby providing evidence that the increased hepatocellular carcinomas observed were closely related to liver toxicity.

The conclusion to be drawn from these studies is that, when considering a substance such as perchloroethylene, which does not react with DNA or is negative in mutagenicity testing (38,39), the critical determinant of carcinogenicity is the level at which organ toxicity is occurring. Without organ toxicity and recurrent tissue injury, the stimulus for increased DNA synthesis and other manifestations of hyperplastic toxicity are removed and excess tumor rates may be expected to disappear.

In other words, one can expect a threshold dose level for the carcinogenic effects of promoting agents at or near the lowest level which produces demonstrable physiological alteration or organ toxicity. Without such manifestations of toxicity, cancer development does not occur. Therefore, if exposure is kept below such a threshold dose level, there should be neither organ toxicity nor any appreciable carcinogenic hazard. Controlling exposures so as to protect workers from organ toxicity will also protect them from cancer.

Closely related to promoting agents is a broader class of modifying agents which may affect bodily defense mechanisms indirectly rather than as the direct effect of hyperplastic or organ toxicity. One example is the induction or suppression of liver microsomal enzymes. Because such enzymes mediate detoxification and/or activation of chemicals, an enzyme imbalance may modify (enhance or inhibit) carcinogenesis. The sedative phenobarbital, which induces liver microsomal enzymes, has been used experimentally to show how enzyme induction can modify the response of chemical carcinogens.*

The common feature of these biological phenomena†, like the hyperplastic or organ toxicity previously discussed, is that they are dose-related and generally exhibit a threshold dose level below which such effects do not occur. Moreover, such effects are generally reversible, the body's defence mechanisms returning to normal once the stimulus is removed. Accordingly, there should be no appreciable carcinogenic hazard from exposure to such modifying agents, provided the dose administered is maintained below the level at which toxicity occurs.

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* For example, phenobarbital administration has been shown to reduce the carcinogenic activity of diethylnitrosamine (40) and aflatoxin (41). A series of studies with the hepatocarcinogen 2-acetylaminofluorene (AAF) have shown that phenobarbital can inhibit or enhance AAF induced liver tumors depending on the dosing sequence (42). Indeed, even in the absence of treatment with known carcinogens, phenobarbital increases tumorigenic response, presumably because of DNA increased synthesis and potentiation of cells initiated by carcinogens occurring naturally in the environment (35,36).

† Another example of such non-genetic mechanisms is depression of the body's immune capability which, as previously noted, may modify tumor induction in certain circumstances.

E. Scientific and Governmental Recognition of Carcinogenic Mechanisms and Thresholds

Leading cancer scientists now generally recognize that carcinogenicity involves different mechanisms (43). Weisburger and Williams of the American Health Foundation recently developed a classification system which divides substances involved in the carcinogenicity process into two broad classes - "genotoxic agents" and "epigenetic or non-genotoxic agents" (44). In a similar scheme, Dr. Albert C. Kolbye, Associate Bureau Director for Toxicological Sciences at U.S. Food and Drug Administration (FDA), recently classified substances involved in the carcinogenicity process as either "genotoxic" or "non-genotoxic" agents depending on their ability to exert genotoxic effects on DNA and cell replication (6). Similarly, Dr. Henry C. Pitot of the University of Wisconsin has stated that initiating agents, complete carcinogens* and promoting agents can be distinguished (45). In this connection, Dr. Robert Squire of Johns Hopkins University has said that there is sufficient evidence to apply judgment to carcinogenic risk on a case-by-case basis (46).

The distinction between the different mechanisms of carcinogenicity has important risk assessment implications, particularly with respect to establishing thresholds (47). For example, Weisburger and Williams have described the critical difference between "genotoxic" and "epigenetic" substances with respect to risk assessment (44):

> "Risk evaluation for the genotoxic agents, by virture of their specific mechanisms of action, must necessarily be different from such an evaluation for agents operating by epigenetic pathways. Genotoxic agents interact with DNA and genetic material.... Once cell duplication with the so generated abnormal DNA has occurred, the reaction is translated into an irreversible alteration in DNA.
>
> In contrast, the action of agents that operate by epigenetic mechanisms, which are subject to much further research, usually requires their presence at high levels for a long time, and indeed is reversible up to a certain point. So far as is now known, their action is also tissue- specific."

Recent scientific studies indicate that threshold levels exist for epigenetic substances (48). According to Stott and Watanabe (49) of The Dow Chemical Company:

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* A complete carcinogen is one capable of both initiating and promoting tumour development.

> "Epigenetic carcinogens display characteristics of thresholds and the cellular responses they evoke are often reversible. These responses are usually only observed upon repeated administration of high metabolically saturating dosages which often result in nonlinear excretion pharmacokinetics."

Similarly Weisburger and Williams (50) have concluded:

> "Most epigenetically acting agents are active only at high, sustained doses and, up to a certain point, the effects they induce are reversible......it may be possible to formulate safe levels of exposure after appropriate toxicologic dose-response studies are conducted."

Thus, the potential risk presented by an epigenetic agent can be essentially eliminated by reducing exposure levels. The safety evaluation of an epigenetic carcinogen, like any other toxicological effect, is done by determining a no-observed-effect-level (NOEL) and applying a suitable safety margin. The application of mathematical modelling techniques such as the one-hit extrapolation model greatly overestimates the cancer risks at low dose.

While genotoxic substances may present a greater potential risk than epigenetic substances, recent scientific literature suggests that practical thresholds (i.e. exposure levels below which a signigicant carcinogenic risk would not be present or, in other words, no-observed-effect-levels (NOEL) can be established for genotoxic agents based on time-to-tumor data and non-linear dose response relationships. At high dose levels where detoxification, excretion or repair mechanisms have been overwhelmed, the relationship between dose and response may be nearly linear because the number of mutations at the cellular level is likely to be roughly proportional to the chemical dose administered. But at low doses, where normal defence mechanisms are operative, one would expect a disproportionate decrease in the effective genotoxic dose due to the success of the body in screening out the initiating agent before it can damage or alter DNA. The one-hit or linearized extrapolating model would substantially overestimate the cancer risk, as shown for vinyl chloride (14) and ethylene dibromide (51).

There is precedent for governments of various countries taking considerations of carcinogenic mechanisms and threshold levels into account in regulating carcinogens. A prominent example is the U.S. Food and Drug Administrator's decision to allow the marketing of selenium as a nutrient in swine and poultry feed even though selenium had been demonstrated to induce liver neoplasms in rats. Thus, the FDA concluded that selenium's capacity to induce liver neoplasms was directly associated with its capacity to induce liver damage when consumed in excessive amounts. According to the FDA, selenium is "no different from a number of foods and drugs available in the marketplace today," including alcohol which "is associated with a higher incidence of liver cirrhosis which, in turn, is associated with a higher incidence of liver cancer."

In the safety evaluation of 2,3,7,8-TCDD, an epigenetic carcinogen, the U.S. FDA (52) and the Dutch Government (53) used the no-observed-effect-level for liver cancer and applied a safety margin to arrive at a safe 2,3,7,8-TCDD level in foods and drinking water. Holland also has a carcinogen policy that recognizes the distinction between genotoxic and non-genotoxic carcinogens. More recently, EPA considered the evidence of a non-genotoxic mechanism with respect to nitrilotriacetic acid (NTA) in permitting its re-introduction into the marketplace.

II. A REALISTIC RISK ASSESSMENT PROCEDURE*

In the past, only chronic carcinogenicity studies have been used for carcinogenic risk assessment, by extrapolation using various statistical models. The frequently used linear one-hit model employs highly conservative assumptions and does not fit well the observed animal test data or human epidemiology data, the model overestimating the true risk.

The various linearized one-hit or multi-stage mathematical models ignore or incorrectly use important data, including:

- The carcinogenic mechanism (genotoxic or non-genotoxic);
- The type of tumor and its relevance to humans;
- The subjectivity of tumor identification;
- Pharmacokinetic data, particularly saturation of detoxification mechanisms resulting in non-linear pharmacokinetics;
- Relevance of the route of exposure;
- The assumption that humans are always more sensitive than animals based upon metabolic rates;
- Human epidemiology studies;
- Using only the most sensitive study for risk assessment, rather than all valid studies (including negative studies).

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* For a full description of this risk assessment procedure, see the American Industrial Health Council report by Colin N. Park and Ronald D. Snee, which is reproduced as an appendix, with Dr. Park's permission.

A complete picture of the carcinogenicity of a chemical requires an analysis of the following kinds of studies:

- Mutagenicity;
- Subchronic studies in Animals;
- Metabolism;
- Chronic studies in Animals;
- Epidemiology;
- Route of Exposure;
- Level of Exposure;

An alternative risk assessment model is proposed (see Table III) which relies on the dose response data in the observed range and the use of safety factors as modified by scientific judgment.

III. THE ESTIMATION OF HUMAN RISK ON THE BASIS OF ANIMAL TEST RESULTS

The key points to be considered are:

(1) Estimation of workplace exposure;

(2) Extrapolation from high dose data to low dose estimates;

(3) Extrapolation from test animals to humans.

(1) Estimation of Workplace Exposure

Data needed for a risk assessment include:

- The nature and size of the human population subgroups exposed to the substance from all sources;

- The amounts of the substance to which such groups are exposed (including averages and high and low figures) from all sources;

- The duration of exposure;

- The route of exposure;

- The proportion of exposure in the workplace population subgroup attributable to workplace exposure;

- Variability in metabolism of the substance.

The regulatory agency cannot treat all persons potentially exposed and all workplaces alike. Thus, if there are different exposure patterns in different workplaces, the risk assessment must take those differences into account.

TABLE III

A REALISTIC RISK ASSESSMENT PROCEDURE

"Base Case" Extrapolation Factor = 1000

(one-hit model)

Mechanism Factor = 1 - 10

Animal-to-Man Factor = 0.1 - 10

NOEL: No-Observed-Effect Level
from animal carcinogenicity tests

$$\text{Acceptable Level For Human Exposure} = \frac{\text{NOEL}}{\text{Extrapolation Factor}} \times (\text{Mechanism Factor}) \times (\text{Animal-to-Man Factor})$$

(2) Extrapolation from High Dose Data to Low Dose Estimates

Assuming that the levels to which workers are likely to be exposed are lower than the levels used in animal tests, the next step is to attempt to extrapolate from test data for high exposures to predict the results which would be anticipated in the same test system from low exposures. It is important to note, however, that if only inadequate or questionable animal test data are available, extrapolation should not be attempted, since the results could be highly misleading. Therefore, the quality of the data must be evaluated with sound scientific judgment.

The following are some of the issues likely to arise:

(a) Suitability of the data:

- Quality of the study;
- Number of species and strains affected;
- Number of tissue sites at which tumor occur;
- Method of exposure;
- Latency period;
- Potency (dose level and duration of exposure required to induce tumors);
- Proportion of malignant, benign and pre-neoplastic changes;
- Sex of animals;
- Significance of results.

(b) Biological characteristics of the test substance:

- Structural similarity to known carcinogens;
- Metabolic and pharmacokinetic data;
- Capacity to bind to DNA, RNA or protein;
- Physiological, pharmacological and biochemical properties;

- Genotoxicity as revealed in short-term tests for mutagenic effects;
- Mechanism of tumor induction;
- How well the data fit the various mathematical models;
- Whether results are the joint effect of two or more agents.

(c) The availability of measured responses and of statistical criterial for evaluating such responses:

- Time-to-tumor data;
- Enzyme levels;
- Degree of tissue degeneration;
- The mechanism of carcinogenesis.

(3) Extrapolation from Test Animal to Humans

Two methods of interspecies extrapolation are commonly used:

- Conversion of dosages to mg/kg body weight per day;
- Conversion of dosages to mg/cm^2 body surface area per day.

Both were used and discussed in the NAS nitrite study.

Issues likely to arise in making an inter-species extrapolation include:

- Metabolic and pharmacokinetic differences between humans and test species;
- Differences in exposure routes;
- Differences in genetic susceptibility to carcinogens in general or to a particular substance in particular;
- Availability of human data.

In conclusion, risk assessment is a complex, multifaceted process that is not easily quantified and, at present, must be based on qualitative as well as quantitative information. It is evident that dose-response modelling of results from chronic studies is of limite value in estimating human risk associated with low-dose chemical exposure because the models represent only one part of the complex process and have no accepted biological basis. As Dr. Arthur Upton, former director of the National Cancer Institute, has commented (54):

> "Standard setting necessitates quantitative inferences about dose-effect relationships which are highly uncertain in our present state of knowledge. It also involves value judgements about the acceptability of risks, which are complicated by philosophical, ethical, socioeconomic, and political differences."

SUMMARY

Understanding the carcinogenic mechanisms involved is critical in assessing the risk of a substance to man. Current knowledge on genotoxic and non-genotoxic (epigenetic) mechanisms of carcinogenesis is reviewed. Present evidence indicates that no-effect levels exist for non-genotoxic carcinogens, and so they can be regulated using a safety margin approach. The evidence also suggests the existence of "practical thresholds" for genotoxic carcinogens.

Exclusive reliance on mathematical extrapolation models such as the one-hit model is scientifically unacceptable for risk assessment purposes. Such factors as the carcinogenic mechanism involved, the animal-to-man factor and the dose-response relationship in animal carcinogenesis test must also be taken into account in any realistic risk assessment procedure.

MONITORING AND CONTROL OF CHEMICAL EXPOSURE IN THE WORKPLACE

INTRODUCTION

The risk presented by a substance depends on its inherent toxicity *and* on the extent to which humans are likely to be exposed. There is nothing we can do to change the toxic properties of a chemical, but we can do a great deal to control human exposure, through engineering controls, improved work practices and personal protection equipment.

MONITORING

An effective exposure control program must begin with accurate and comprehensive monitoring to identify exposure levels and sources of exposure. Operations to be examined include:

- Raw material unloading and storage;
- Raw material sampling;
- Laboratory testing;
- Process Sampling;
- Maintenance;
- Product drumming;
- Product bulk loading and shipping.

Two main categories of monitoring are personnel monitoring where the sampling device is attached to the worker's person, and area monitoring, using stationary devices.

Personal Monitoring

A typical sampling device comprises a battery-powered diaphragm pump, worn on the belt, connected to a sampling tube containing adsorbing material, attached to the worker's collar. This technique is used:

- to determine time-weighted average (TWA) exposures;
- to determine short-term exposures;
- to evaluate work practices involving particular tasks, equipment or individuals;

- to measure effect of engineering controls or changes in work practices.

By sampling for the entire work period, samples collected in the employee's breathing zone document his potential TWA average exposure. This is not necessarily his true TWA because respiratory protection may have been used, but it gives "worst case" data.

Some shortcomings of currently available equipment and techniques are:

- the level of potential exposure is known only after the fact;
- there is no indication of maximum concentrations encountered when the monitoring device is used for TWA measurements;
- no warning is given on entering an area where concentrations are above acceptable levels.

Area Monitoring

Sampling devices strategically located throughout the workplace provide a detailed record of air contaminant levels; if located close to potential emission sources they act as leak detectors to provide early warning of workplace contamination. The devices can vary from self-contained units, similar to the personnel sampling devices, to sophisticated centrally operated continuous area monitoring systems, described below.

A centralized automatic analyzer sequentially collects and analyzes many air samples each day from many locations throughout the plant. The equipment might include a magnetic tape memory system, a teletype/punched tape output, and a programmable calculator to control the system. The computer instantaneously compares each result against a programmed alarm level. If this level is exceeded, an audible and visual alarm occurs, which require a manual acknowledgement to cancel them. Benefits of a centralized area monitoring system include:

- Year-round, 24 hours/day surveillance;
- Better control of plant operation;
- Early detection of leaks;
- Warning of areas not be entered without respiratory protection;
- Detailed statistical information on long-term trends.

Because of its high cost (around $100,000) this type of equipment is not for use in every production unit.

MINIMIZING EXPOSURE IN THE WORKPLACE

Engineering Controls

Once the monitoring program has identified individual pieces of equipment or specific operations associated with unacceptable exposure levels, the use of engineering controls to eliminate the exposure source should be considered as the primary control method. The following are some examples of engineering controls we have successfully used at Dow Canada:

- Closed loop sampling systems;
- On-stream analyzers;
- Vacuum duct located at drum opening to withdraw vapours during drum filling;
- Closed systems to evacuate/drain/purge/steam equipment in preparation for vessel entry and maintenance;
- Relocation of potentially hazardous storage facilities to low population density areas of the plant;
- Replacement of older equipment with modern units requiring less maintenance, lowering exposure potential;
- Emergency block valves to isolate malfunctioning equipment are remotely operated, eliminating potential exposure;
- Magnetically driven or sealless pumps to eliminate leakage via conventional pump seals;
- Control valves with double stem packing, the space between being vented to a collection system.

After engineering controls have been installed, their effectiveness in reducing contamination in the workplace can be evaluated by means of area and personal monitoring.

Administrative Controls

Development and enforcement of operational procedures are an important part of the health and safety program. In preparing for maintenance work, for example, the following procedures have long been practised at Dow plants:

- Entering vessels requires special and elaborate procedures, including thorough steaming and air purging followed by testing of the atmosphere for presence of flammable vapours, oxygen content and to ensure that chemical levels are well below the TLV. If low exposures cannot be guaranteed, fresh air masks must be worn.

- A system of safe work permits ensures that no maintenance work can begin until plant operators have confirmed in writing that the equipment has been thoroughly purged and checked.

- A tagging procedure isolates equipment so that it cannot be operated while maintenance work is in progress.

Personal Protective Equipment

Even though the chemical industry is committed to reducing reliance on respiratory protection as a primary means of exposure control, there are circumstances where respirator use is unavoidable, for example:

- as a means of protection for emergency egress;

- as a means of protection when engineered control of the work environment is impractical;

- as a backup to existing engineering controls;

- for non-routine, rarely performed maintenance jobs;

- when an employee requests it.

An integral part of any respiratory protection program, besides ensuring that proper and adequate equipment is available, is the fitting and training of workers in its effective use. Training includes the procedures for proper use and communication on the limitations of the various types of respirator employed. A special respiratory training facility is used for training and testing employees in the correct fitting and use of respiratory equipment.

Employee Education and Training

The Dow Chemical Company has long recognized the importance of a comprehensive approach to chemical hazard management through safety, health and loss prevention programs at each manufacturing location. At each location, supervision in each manufacturing unit is charged with implementing and maintaining an active health and safety program for operating and maintenance personnel. A key part of this program is the education and training of workers on the hazards of the materials in that unit. Through this continuous educational program, the employees are constantly aware of their individual responsibility for ensuring that safety standards are never by-passed by themselves or their fellow workers and that protective equipment is properly used and maintained.

Employee suggestions on ways to improve safety procedures and engineering controls are actively solicited.

Each manufacturing unit is responsible for communicating to its personnel annually updated hazard information for process chemicals. Data sheets are provided that contain much of this chemical hazard information. Progress on this annual communications program is tracked by a monthly index system. Included in the hazard information communicated to employees are the results of industrial hygiene surveys to assess employee exposure levels.

New employees are given an orientation training program which includes a detailed presentation on the Dow Industrial Hygiene Program and the hazards of major chemicals handled in the various plant sites. Operator progression training requires the completion of various training modules related to safety and health programs before new employees can advance in jobs classification.

Each manufacturing unit holds meetings with contract personnel before a contract job is started to outline and discuss job safety rules or procedures and to identify any chemical hazards that may be encountered on the job. Before contractors begin a job involving operating equipment, it is thoroughly drained, steamed and purged. If monitoring is needed and the contractor lacks the expertise, Dow provides this technical back-up.

Health Surveillance

No monitoring program is complete without appropriate health surveillance of the work force. This program should meet the needs of any general work population but must include specific health monitoring to ensure the effectiveness of the industrial and plant hygiene monitoring and safety programs. Details of Dow's health surveillance program will be included in our oral presentation.

SUMMARY

Area and personal monitoring ensure the quality of the air in the workplace and identify unacceptable potential exposures. Engineering controls are the primary means and administrative procedures the secondary means for reducing these potential exposures. Personal protective equipment is used only as a back-up or when control methods are impractical. Employee education and training is essential, the well informed employee being critical to the success of any control program.

COMMENTS ON THE DISCUSSION PAPER

"THE CONTROL OF WORKPLACE CARCINOGENS"

Rather than present a detailed critique of this paper, we would like to focus attention on a few major points of special concern.

p.2 The statement in parentheses at the foot of p. 2:

> ".....very few cancers can be cured by medical treatment once an individual is affected"

should surely be amended to:

> "....very few *internal* cancers can be cured by medical treatment....."

p.5 The discussion paper strikes a positive note by citing the example of the nuclear power industry's enviable record of success in controlling worker exposure to ionizing radiation. It is important, however, to draw a clear distinction between the carcinogenic effects of radiation and those of chemicals. Ionizing radiation, which passes readily through tissues and membranes directly to the genetic material of the cell (DNA), at relatively low doses may produce small but finite increases in cancer.

In contrast to ionizing radiation, chemicals which produce cancer must elude various bodily defence mechanisms (generally inoperative against radiation) before reaching the genetic material of the cell. If a carcinogenic response is produced by a chemical only at high dose levels, where bodily defense mechanisms are overwhelmed, then the chemical may, depending upon the carcinogenic mechanism, pose no carcinogenic risk at the subtoxic dose levels encountered in everyday experience.

No-observed-effect levels for chemical carcinogens can be established in chronic toxicity-oncogenicity studies in animals in exactly the same way as they are established for any of the other toxicological manifestations. Safety margins established for non-carcinogens may or may not be adequate for chemicals which are shown to be carcinogens. Depending upon the carcinogenic mechanism, it may be necessary to establish higher safety margins for certain chemical carcinogens. However it should be quite possible to establish some safety margin for chemical carcinogens, below which there is no measurable or detectable risk to the population. This concept is different from the ALARA principle (bring exposures down as low as reasonably achievable) in radiation hazards. This distinction should not be overlooked in policy development.

Furthermore, chemical carcinogens cannot be dealt with generically. Chemicals induce carcinogenesis by different mechanisms (10) and exhibit a million-fold range of potency in animals (55).

p.10 We agree with the philosophy (line 3) that all new chemicals should be screened, but not that all carcinogens or potential carcinogens should be regulated.

The key issue is not carcinogenicity *per se*, but the safety of the worker, which depends on both the potency of the carcinogen and the potential level of human exposure in the workplace. This principle is now firmly established in the U.S.:-

> "....OSHA cannot promulgate a regulation for a carcinogenic substance solely because the substance has been *identified* as a carcinogen, based on either human or animal evidence. According to the Supreme Court's decision in the benzene case, before OSHA can promulgate any permanent health standard, the Secretary of Labor is required to make a determination that a place of employment is unsafe in the sense that a significant risk to workers is present and that this risk can be eliminated or lessened by the promulgation of a standard or a change in a standard. In that case, benzene was a proven human carcinogen based upon human evidence. Nevertheless, the Court vacated OSHA's benzene standard because OSHA did not meet its statutory burden to show that long-term exposure to benzene, at the levels encountered in the workplace, presented a significant risk of material health impairment." (56).

In discussing the screening of new chemicals, mention is made of carcinogens, potential carcinogens and suspected carcinogens. The distinction between potential and suspected carcinogens is not clear. This classification should, of course, be precisely defined by the tier testing system (see Figure 1). In general, the term carcinogen should be qualified by making a distinction between animal carcinogens (i.e. those giving positive results in tier 3 testing) and human carcinogens (based on positive epidemiologic data).

p.11 last para. "This [risk] assessment should be based in part on the tumor-inducing potency of the compound in animals."

We would like to see added, the words:

> "and in part by the potential for human exposure."

The risk presented by a substance depends on its inherent toxicity *and* on the extent to which humans are likely to be exposed to it. We are concerned that too little emphasis is placed on the importance of measuring and controlling human exposure in the workplace.

p.12 Our comments on the proposed classification scheme are on p. 171.

p.13 The "one tonne rule" may be attractive from the viewpoint of administrative convenience but in real life there is no simple relationship between production volume and potential for human exposure. A chemical formed as an intermediate in a closed reactor which is immediately converted to a final product (without ever leaving the reactor) is of little consequence as a health hazard. On the other hand, a trace impurity formed as an unwanted by-product may present a serious health threat. Convenient though the one tonne rule may be, there is no substitute for enlightened professional judgment.

p.13 last para. The concept that substances should be assessed "as used" is ideally correct. Toxicology tests are often run on technical grade rather than purest available chemicals. If such tests are positive, subsequent tests on the pure material can establish whether the carcinogenic effect was caused by the chemical itself or by impurities. On the other hand, it is not practical to run tests on formulated products because of frequent variations in composition, formulation changes, etc.

Structural similarity to a known carcinogen and the tendency of a chemical to accumulate in tissue are valuable indicators in assessing probable carcinogenicity but, *by themselves*, are not sufficiently unequivocal indicators on which to base 3-5 year animal studies costing around a million dollars.

For example, many compounds that are fat-soluble are cleared rapidly from the body when exposure decreases. Those compounds that accumulate and have *prolonged half-lives* should be candidates for chronic toxicity testing.

Structural similarity to known carcinogens is one of a number of "triggers" which should alert the investigator to the need for further testing, but more than one such trigger should be needed (see p. 145 and Fig. 1).

p.14 In line 3, the use of the word "non-positive" implies a lower degree of certainty* than the word "negative". If a test does not give a positive result, it is normal practice to characterize that result as negative.

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* Reminiscent of the three verdicts in Scottish jurisprudence: guilty, not guilty, and non-proven.

The statement is made that "where tests are proved non-positive the results could be referred to the Advisory committee which would advise the minister on whether the substance should be placed in Category II or III." While we do not endorse categorization, we comment that if all the prescribed tests are negative, surely the substance should automatically go into Category III.

p.14 para.2 The statement is made:

> "if members of the committee had any doubts whatsoever about the safety of a substance, the appropriate recommendation would be to place it in Category II."

This 'rule of the doubtful minority' would allow one member with one doubt to place a chemical in Category II, thus assuring the expenditure of $800,000 to $1,100,000 for long-term animal tests. Furthermore, the present wording virtually guarantees that all new chemicals will be placed in Category II, because committee members will quite understandably err on the side of extreme conservatism to avoid any risk of error.

Science is based not on certainties but on the systematic management of probabilities. The wording "any doubts whatsoever" should be modified to

"any reasonable doubt,"

an expression frequently used and clearly understood in our courts.

p.15 para.1 The statement is made:

> "If the results of the short-term tests were non-positive, the manufacturer or user should have the option of either putting the substance into long-term animal tests or having it referred to the advisory committee."

As noted above (p.14, para.1), if all the prescribed tests are negative, the substance should automatically be put into Category III.

p.18 In the section entitled "Chemicals Not Considered New", the opening paragraph contains the sentence:

> "The Ministry, in consultation with the Advisory Committee, should determine which of the substances on the EPA list or currently in use in Ontario have not been adequately assessed for their potential carcinogenicity. Priorities should be set for testing of such substances. Expenses of such testing should be borne by the manufacturer of a substance currently in use in Ontario."

There are a large number of existing chemicals in current use but a limited number of testing laboratories, toxicologists, animal pathologists, support staff and test animals. The problem calls for international cooperation in the setting of priorities to ensure that these limited resources are applied to the most serious data gaps.

Unilateral action by Ontario would have little impact on an international problem of this magnitude. We cannot expect to exert much influence on the testing priorities of the western world or expect chemical manufacturers to devote scarce testing resources to carrying out tests required only in Ontario. The net effect of such arbitrary measures as "classifying an old chemical as new when it is used in a new plant, new process, or at the end of five years" would be to ban the import of raw materials essential to the well-being of Ontario's manufacturing economy.

COMMENTS ON
"ISSUES FOR CONSIDERATION"

Issue #1 National and International Coordination and Cooperation in the Control of Carcinogens

1. Question: *Should representation be made, through the appropriate channels, to the federal government calling for assistance in the financing of individual provincial initiatives and for the establishment and co-ordination of a nationwide carcinogen program, through agencies such as the federal Department of Labour, the Department of National Health and Welfare and the Canadian Centre for Occupational Health and Safety?*

   Answer: We agree that a nationwide carcinogen program is desirable.

2. Question: *As part of a national program, should the federal government or national agency be encouraged to give the highest priority to the objective of assembling and co-ordinating the available data from this and other jurisdictions, with regard to the carcinogenicity and potential carcinogenicity of chemical substances.*

   Answer: We agree that this is a worthwhile objective but question why it should be given precedence over the study of other health threats in the workplace.

3. Question: *In establishing priorities for the testing of chemicals and in deciding upon permissible exposure limits, should the Ontario Ministry of Labour work in close collaboration with international organizations such as the International Labour Organization? Should due regard be paid to international agreements such as the ILO 'Convention concerning prevention and control of Occupational Hazards caused by Carcinogenic Substances and Agents'?*

   Answer: Determining priorities for testing and the setting of permissible exposure limits should be based on the best available scientific data from all sources. In this connection we note that the ACGIH is internationally recognized as the foremost organization for setting permissible limits.

Issue #2 Advisory Committee

Question: *Should an advisory committee be established with the responsibility for advising the Minister (or the Ministry) on all aspects of the regulatory program for carcinogens? In particular, should the advisory committee make recommendations with regard to the appropriate categories and controls for chemical substances? Should the criteria applied by the committee be subject to periodic review by the Ministry?*

Answer: We agree on the need for an advisory committee but make the following recommendations:

- The committee should be made up of appropriately qualified scientists from academia, government, industry and labor.
- The committee should concentrate on advising the Minister on scientific issues, such as providing critical reviews on the adequacy of data and the validity of test methods.
- Regulatory matters should be the sole responsibility of the Ministry of Labour.

The criteria applied by the committee should be subject to periodic review by the Ministry.

Issue #3 Reporting Requirements for New Chemicals

Question: *Should the Minister establish reporting requirements for full disclosure of the possible carcinogenicity of any new chemical to be introduced into the workplace in Ontario?*

Answer: Reporting requirements for disclosure of the possible toxic effects of any new chemical introduced into Ontario workplaces are already specified under Section 21 of the Occupational Health and Safety Act.

Issue #4 Testing Requirements for New Chemicals

Question: *Should the Minister establish regulations calling for the examination of all new chemicals on the basis of their chemical structure and relationship to known carcinogens? Following such initial assessment, should all new chemicals (with the exception noted in #3 above be subject to testing requirements as outlined on pages 12-16 .above?*

Answer: No. Chemical structure and relationship to known carcinogens should be only one factor in the examination of new chemicals which should be approached on a case-by-case basis. Our views on the testing of new chemicals are set forth in the section "Testing Methods for Carcinogenicity".

Issue #5 Testing Procedures

1. *Should a standard testing program be developed by the Ministry in consultation with the advisory committee?*

2. *If such a program were to be developed, should it incorporate any or all of the following requirements:-*

   a) *Where long-term animal tests were required, should the procedure outlined in the National Cancer Institute (USA) "Guidelines for Carcinogen Bioassay in Small Rodents", 1976, be followed?*

   b) *Where required, should a minimum of two appropriate short-term tests be conducted on a substance?*

   c) *Should such tests be carried out on commercial samples of chemicals rather than on purified preparations (or in addition to)?*

   d) *Should the formal testing requirements, both for long-term animal tests and for short-term in vitro tests, established by the Ministry, be reviewed every three years?*

Answer: Dow's views on testing procedures are discussed in considerable detail in the section "Testing Methods for Carcinogenicity."

Issue #6 The Classification of New Chemicals

Question: *Should all new substances be placed in Categories I (carcinogens), II (suspect carcinogens) or III (non-carcinogens) according to the criteria set out on pages 12-16 above?*

Answer: We disagree with the criteria for the classification of new chemicals proposed in the discussion paper. Our views on a more desirable regulatory approach are set forth in the Section "Testing Methods for Carcinogenicity".

The Discussion Paper does not provide criteria for the determination of a "known" or "suspect" carcinogen, or of a "non-carcinogen". The problem with the proposed categorization scheme is that a simple, practical definition of those terms is presently impossible: For example:

- Are positive results in an animal carcinogenicity test sufficient to categorize a chemical as a "known" carcinogen?
- What is a "positive" result?
- How many positive results are necessary?
- How does the quality of the animal bioassay affect the categorization of the chemical?
- What if there are both positive and negative bioassays?
- Can the results be properly extrapolated to humans?

Similar problems would occur in attempting to distinguish between "suspect" carcinogens and non-carcinogens. And if the categorization is applied to old chemicals as well, then questions arise concerning the relevance and quality of epidemiology studies, and their consistency with the animal data.

Moreover, as toxicological considerations are only one part of the risk assessment equation, a classification scheme based or the carcinogenic properties of a chemical, without prope consideration of the nature of chemical exposures to the worker will give an inaccurate estimate of the true carcinogenic risk For example, a "known" carcinogen to which workers have very lo exposure may be of less concern than a "suspect" carcinogen wit high exposure. The importance of exposure for risk assessmen purposes is discussed in the section, "Carcinogenic Ris Assessment".

Finally, in the regulatory decision on how to manage a potentia carcinogen, consideration should be taken of the benefits of th chemical.

In sum, given the myriad of complex considerations proper involved in an evaluation of carcinogenic risk, a gener approach to regulation is not feasible. Rather than devoti energy to the difficult and unrewarding task of putting chemical into one of three broad categories, chemicals should evaluated on a case-by-case basis and permissible exposure leve set on the basis of all relevant considerations.

Issue #7 The Control of New Chemicals

If the classification scheme referred to in Issue #6 is thought to be appropriate, should the following measures be adopted:

1. Question: *Where a substance is placed in Category I, should its use be regulated?*

Answer: See our answer to Question 6 above. New chemicals should be evaluated for carcinogenic risk on all relevant considerations, a decision made whether there is sufficient evidence to merit regulating the chemical on the basis of possible carcinogenesis and, if so, what the permissible exposure level should be.

2. Question: *Where a suitable substitute for a Category I substance is available for one or more uses, should occupational exposure to the Category I substance be permitted for those uses?*

Answer: Our previous answers indicate our disagreement with the use of categories. Chemicals should only be allowed for use in the workplace if they can be handled safely. The use of substitutes should be routinely left to the marketplace, since chemical manufacturers have strong incentives to use the safest chemicals. Moreover, we think government regulators are not well positioned to determine the suitability of a substitute. A great number of factors –— product performance, compatibility with other chemicals, patent position, security of supply, cost, ease of handling, flammability, the competitive environment, etc.—- go into the decision to use or manufacture a chemical in the workplace. The "suitability" of a substitute should be assessed on the same basis as that of the originally chosen chemical. These decisions are difficult enough for the user of the chemical; it would be a very hard if not impossible task for regulators unfamiliar with the technological and commercial nuances of chemical manufacturing to make responsible and practical decisions as to the adequacy of substitutes.

Any proposed substitute should be subjected to the same testing scheme as the original substance. This may seem obvious, but it is a point which was overlooked in the early seventies when phosphates in detergents were replaced (wholly or in part) by NTA, a synthetic chemical whose health and environmental characteristics were much more poorly understood than those of phosphates.

3. **Question**: *Where it is determined that a Category I substance is needed and that no suitable substitute is available, should its use be permitted, with the requirement that there be no detectable exposure of the workforce, or should permissible exposure limits be set?*

   Answer: The determination of a permissible exposure limit should never be based on the sensitivity of available analytical methodology. It is not practical to specify "no detectable exposure" because limits of detection are rapidly decreasing as analytical technology advances. Permissible exposure limits should be divorced from detection limits (convenient though they are) and expressed as some reasonable fraction of the no-observed-effect-level.

4. **Question**: *Should Category II substances be treated as suspect carcinogens?*

   Answer: See our answer to Issue #6 above.

5. **Question**: *Should permissible exposure limits be set for Category II substances?*

   Answer: Ideally, permissible exposure limits should be set for every substance to which people are exposed in the workplace, but practical limitations dictate the need for prioritization.

6. **Question**: *Should the appropriate standards be met through the use of engineering and work practice controls?*

   Answer: See section on Monitoring and Control of Chemical Exposure in the Workplace for our general views. The Ministry of Labour has dealt with this issue in Section 4 of their regulations respecting designated substances. The regulations were drafted after a spirited comment period involving both industry and labour organizations. Although Dow does not agree with all aspects of the final regulation, in our view they represent a reasonable compromise between differing viewpoints and should be included in a Carcinogen Policy.

7. **Question**: *Should the use of personal protection equipment be reserved for maintenance purposes and for emergency use only?*

   Answer: Any responsible company develops its own guidelines on the wearing of personal protective equipment. This will include, in addition to emergencies, certain unscheduled maintenance operations and other non-routine activities when exposure potential is temporarily increased. Personal protective equipment should be used to complement, not replace, engineering controls and workplace practices.

8. Question: *Should suitable epidemiological surveillance be maintained for Categories I and II substances?*

Answer: The question is vague with regard to the definition of suitable epidemiological surveillance. We recommend a regular health surveillance program for all employees who are at risk of exposure to potentially toxic substances. Epidemiological evaluation is part of any complete health surveillance program (see p. 169)

9. Question: *Should the use of Category III substances be permitted without surveillance or restrictions unless such measures were required for other purposes?*

Answer: It is our conviction that people who work in industry should have the opportunity for participation in a health surveillance program. Those employees who have potential for exposure to chemicals known to be toxic should, of course, be examined more frequently.

Issue #8 The Testing and Classification of Chemicals Not Considered New

1. Question: *Should the Ministry, in consultation with the advisory committee, determine which of the substances on the EPA list or currently in use in Ontario have not been adequately assessed for their potential carcinogenicity?*

Answer: Yes. We note, however, that a large proportion of the chemicals on the EPA list of existing chemicals have never been and probably never will be used in Ontario workplaces.

2. Question: *Should priorities be set for testing of such substances?*

Answer: Priorities should be set on the basis of the following criteria:

- Number of people chronically exposed;
- Level of exposure;
- Inherent toxicity;
- Nature of the chemical --- persistent, bioaccumulative.

3. Question: *Where it is considered necessary to test a substance currently in use in Ontario, should the cost of such testing be borne by the manufacturer?*

   Answer: We agree that the cost of testing should be borne by the manufacturer of the chemical. Where there is more than one manufacturer, however, the cost should be shared. In our view, the Ministry could perform a valuable service in coordinating such cost-sharing arrangements.

4. Question: *Where a chemical which is not considered new is to be used in a newly-constructed workplace, should it be automatically subjected to the same testing and classification procedures as employed for new chemicals?*

   Answer: The Discussion Paper makes a clear distinction between old and new plants. We recognize that the construction of a new plant provides Ministry officials with a useful administrative "trigger", but we feel strongly that workers at both old and new plants should be provided with the same degree of protection from over-exposure, the same industrial hygiene monitoring, medical surveillance, etc. The only significant difference between old and new plants is that engineering controls can be incorporated into the design of a new plant. With an old plant, such improvements have to be retrofitted, often at much greater cost and, in some cases, lower effectiveness.

5. Question: *Should the Ministry make a systematic attempt to have the substances on the EPA list and those currently in use in Ontario properly categorized, according to the classification system outlined above, within a period of five years, making full use of information developed in other jurisdictions?*

   Answer: We agree in principle, but feel that five years is an overly ambitious deadline. Furthermore, we are not convinced of the practical value of the classification scheme proposed in the Discussion Paper (see our comments on p. 177-178).

Issue #9 The Control of Chemicals Not Considered New

1. Question: *Where a chemical, not considered new, is placed in Category I, where it is sufficiently beneficial to justify its continued use and no suitable replacement is available, should it be treated as follows:*

   a) When used in a new plant, should it be subjected immediately to the same regulatory controls as are employed for new substances?

   b) When used in an existing plant, should it be subjected immediately to appropriate regulatory controls?

Answer: If the use of a carcinogenic chemical is deemed to pose a significant hazard in the workplace, the chemical should be considered as a designated substance under the Occupational Health and Safety Act. If its use poses no significant hazard, the Ministry should set exposure guidelines only (see the flow chart, Fig. 1, in the section "Testing Methods for Carcinogenicity"). These comments apply to the use of carcinogenic chemicals in old or new plants, without distinction, for the same reasons as we gave in our answer to Issue #8, question 4 (see p. 182).

2. **Question:** *Where a chemical, not considered new, is placed in Category II, should it be treated as follows:*

   a) When used in a new plant, should it be subjected immediately to appropriate regulatory controls?

   b) When used in an existing plant, should it be subjected to somewhat less stringent regulatory controls for an initial period?

   Answer: Non-new chemicals, for which there are insufficient data on which to base carcinogenicity assessments, should be given exposure guidelines applicable without distinction to old and new plants.

3. **Question:** *After an initial period of five years, should all users of chemicals which are not considered new be required to meet the standards set for new chemicals, regardless of whether the substances are to be used in new or existing plants?*

   Answer: The scope of the question is far too broad. The expressions "all users of chemicals which are not considered new", even if confined to the workplace situation, would cover cleaning materials used by industrial janitors, turpentine used by painters, Varsol used by auto mechanics and a host of other everyday products. In our view, it would be impossible to test all old chemicals within five years.

Issue #10 Epidemiologic Surveillance

1. **Question:** *Should the Minister ensure that appropriate epidemioligic surveillance be provided where individuals are known to have been exposed to established or suspect carcinogens?*

   Answer: See our answer to Issue #7, question 8 (p. 181).

2. Question: *Should employers be required to establish group and individual exposure records suitable for epidemiological surveillance?*

Answer: We agree that suitable records for epidemiological surveillance should be maintained. It must be understood, however, that individual exposure records will not be possible for all chemicals and may be unnecessary for many. We will continue to maintain exposure records based on the judgment of our health professionals regarding exposure potential and toxicology. Chemicals in each of our plants are reviewed yearly on the basis of their exposure potential and hazard rating. Details will be given in our oral presentation.

3. Question: *Should the Minister seek to ensure that appropriate resources are made available to the Ontario Cancer Treatment and Research Foundation in order to guarantee continuance of the Ontario Cancer Registry?*

Answer: Yes.

Issue #11 The provision of Information to the Workforce and to the Public

1. Question: *Should the Ministry ensure that members of joint health and safety committees, or members of the workforce where no committees are established, are provided with information, not only on potential hazards but also concerning the chemical structure of any new substance, regardless of whether it is considered by the employer to be safe?*

Answer: Dow is committed to thoroughly communicating the potential hazards of workplace chemicals to its employee. Informing people of the nature of the materials with which they are working is perhaps the most important aspect of our occupational health program. We have established several programs, described in detail in the section "Monitoring and Control of Chemical Exposures" in the Workplace, to achieve this purpose and we believe these programs have been extremely effective.

Nevertheless, we have some major concerns should the Ministry, through a Carcinogen Policy, impose major changes in our present hazard communication policy. Our colleagues in Dow U.S. have reviewed detailed proposals from the United States Occupational Safety and Health Administration regarding hazard communications; while generally agreeing with the intent of OSHA program, they have found much of the proposed program impractical and very burdensome with no gain in useful information going to the employee. While not contending our programs should be above government review, we do feel strongly that, because of our greater familiarity with the workplace, the most effective hazard communication programs will be those developed by the employer working with the employees.

Another major concern in establishing a hazard communication program is the potential loss of trade secrets. Many trade secrets represent literally millions of dollars of research investment and potential commercial return. In establishir a hazard communication program, a balance must be struck between the workers legitimate right to know about workplace hazards and the company's legitimate right to protection of trade secrets. For example, disclosing chemical structures to workers has at best a very slight effect on the worker's awareness of chemical hazards while having a tremendous potential for the loss of valuable trade secrets.

The issues surrounding the workers' (and public's) right to know about chemical hazards are complex and call for difficult judgments. We urge that attempts to draft policy in this area be done with great care and only after considering the views of interested parties.

2. Question: *Should the Ministry establish a procedure to ensure that details of the chemical structure and health effects produced by a new substance are available to the joint health and safety committee (or the workforce), in the event that management fails to provide this information?*

   Answer: See our answer to Question 1 above.

3. Question: *Should the Minister urge the government of Canada to work with industry, with workers and with the Canadian Centre for Occupational Health and Safety to develop a labelling and colour-coding system which would alert users and members of the workforce to the presence of a carcinogen or suspect carcinogen in any substance to be used?*

   Answer: See our answer to Question 1 above.

   While not opposing the principle of labelling carcinogens, we can envision (as is true of some current proposals in the United States) labelling programs that are burdensome, cost-ineffective and add very little if anything to the protection of the worker.

4. Question: *Should the Minister make available to the public an index of new substances showing the categories in which they have been placed? Should the data base which has led to this categorization also be made available for public scrutiny?*

   Answer: In our answer to question 6 we have explained our opposition to the suggested categorization scheme. As we understand the suggested categories, a chemical might be listed as a "suspect" carcinogen that could in fact be used safely with great confidence. An unfair and damaging stigma could thus surround a chemical, damaging its commercial development.

The data base supporting the risk assessment of a chemical could be made public, but it should be in summary form, to respect the legitimate rights of companies to confidentiality of their trade secrets. Publication of the complete details of the toxicological testing would lead to unfair competition. It would allow a competitor to seek federal registration of an identical product by using, at no cost, toxicological data which cost the originating company hundreds of thousands of dollars.

5. Question: *Should the confidentiality provisions of section 34 (1)(b) of the Act apply in the case of carcinogens, or should there be full disclosure of all available information to the workforce and to the public?*

Answer: We support the law as written and would be strongly opposed to a full disclosure of available information without due consideration of trade secret protection.

ssue #12 Penalties for Non-Compliance with the Regulation

Question: *Should an employer who introduces a known or suspect carcinogen into the workplace and fails to meet acceptable standards be liable to a penalty in excess of those currently available under section 37 (1) of The Occupational Health and Safety Act?*

Answer: We see no justification for treating carcinogens any differently than other potential hazards covered under Section 37 (1). Moreover, the considerations that go into the setting of penalties can be very complex and fall properly within the legislative function. For example, it would not be legally permissible to impose a penalty based on terms as vague as "suspect" carcinogen or "acceptable standards".

Issue #13 Research

Question: *Should provision be made for the relaxation of the regulatory requirements in order to permit research in the following areas:*

a) research targetted toward the development of new chemicals?

Answer: This question is very difficult to answer without knowing what the regulatory requirements will ultimately be and what form a "relaxation" of those requirements would take. As a general matter, research workers are obviously entitled to the protection enjoyed by other workers in Ontario. On the other hand, the duration and degree of exposure of research workers to chemicals may differ markedly from exposures of workers in manufacturing plants.

The synthesis of a new chemical by its very nature involves unknown risks. Consequently, laboratory workers should be trained to handle new chemicals with extreme care to minimize personal exposure. If development of a newly synthesized chemical is to continue, then in the tier testing scheme which we have proposed (see Figure 1 in the section "Testing Methods for Carcinogens") an initial risk assessment is done. If, as would normally be the case with chemicals in the development stage, exposure is insignificant, then limited reporting would be required (unless the new chemical was a variant of a GRAS compound). When exposure is expected to become significant, then Tier 1 testing would commence.

Also bearing importantly on this issue is the consideration that excessive and costly regulation in the research stage will stifle the development of potentially useful chemicals and drugs.

b) medical research involving the use of carcinogens for scientific or therapeutic purposes?

Answer: This activity is outside the scope of Dow's operations in Ontario.

REFERENCES

1. Doll, R., & Peto, R., "The Causes of Cancer: "Quantitative Estimates of Avoidable Risks of Cancer in the United States Today", J. Nat. Cancer Inst. 66, 1191-1308, (1981), p. 1256, Table 20.

2. Ibid. P. 1245.

3. Schmidt-Bleek, F., "Regulated Testing of New Substances for Environmental Exposure and Toxicity in the European Community", Regul. Toxicol. Pharmacol. 1, 123-146, (1981).

4. OECD Guidelines for Testing of Chemicals Published by the Organization for Economic Cooperation and Development, Paris, 1981.

5. EPA Toxic Substances Control Act, Section 4, Support Document Test Data Development Standards: Chronic Health Effects, Published by the United States Environmental Protection Agency, Washington, D.C., 1979.

6. Kolbye, A.C., "The Application of Fundamentals in Risk Assessment," Paper delivered at American Chemical Society Symposium on Pesticide Chemist and Modern Toxicology, (June, 1980).

7. Cornfield, J., "Carcinogenic Risk Assessment," Science 198, 693-699, (1977).

8. Gehring, P.J. & Blau, G.E., "Mechanisms of Carcinogenesis: Dose Response," J. Environ. Pathol. Toxicol. 1, 163-179, (1977).

9. Roe, F.J.C. & Tucker, M.J., "Recent Developments in the Design of Carcinogenicity Tests on Laboratory Animals," Int. Congr. Ser. - Excerpta Med. 311, 171-177, (1974) (Ex.835).

10. Weisburger, J. & Williams, G., "Chemical Carcinogens", Ch. 6 Casarett & Doull's Toxicology: The Basic Science of Poisons, (1980).

11. Fox, J.L., "Immunology: Complexity Yielding to Research," Chem. Eng. News 18-22, (September 22, 1980).

12. Maltoni, C., Proceedings of the 20th Meeting, Club de Cancerogenese Chimique, Paris, November 10, 1979.

References, cont'd....

13. Buchter, A., Filser, J.G., Peter, H., & Bolt, H.M., "Pharmacokinetics of Vinyl Chloride in the Rhesus Monkey," Toxicol. Lett. 6. 33-36, (1980).

14. Gehring, P.J., Watanabe, P.G., & Park, C.N., "Risk of Angiosarcoma in Workers Exposed to Vinyl Chloride as Predicted from Studies in Rats," Toxicol. Appl. Pharmacol. 49, 15-21, (1979).

15. Reitz, R.H., Quast, J.F., Watanabe, P.G., & Gehring, P.J., "Chemical Carcinogens: Estimating the Risk," Science 205, 1206-1208, (1979).

16. Fox, A.J., & Collier, P.F., "Mortality Experience of Workers Exposed to Vinyl Chloride Monomer in the Manufacture of Polyvinyl Chloride," Br. J. Ind. Med. 34, 1-10, (1977).

17. Equitable Environmental Health, Inc. Epidemiological study of vinyl chloride workers. Final report submitted to Manufacturing Chemists Assoc., Washington, D.C., (1978).

18. Ott, M.G., Langner, R.R., & Holder, B.B., "Vinyl Chloride Exposure in Controlled Industrial Environment," Arch. Environ. Health 30, 333-339, (1975).

19. Chiazze, L., Nichols, W.E., & Wong, O., "Mortality among Employees of PVC Fabricators," J. Occup. Med. 19, 623-628, (1977).

20. Kramer, C.G., & Mutchler, J.D., "Correlation of Clinical and Environmental Measurements for Workers Exposed to Vinyl Chloride," Am. Ind. Hyg. Assoc. J. 33, 19-30, (1972).

21. Farber, E. & Solt, D., "A New Liver Model for the Study of Promotion", In T.J. Slaga, A. Sivak, R.K. Boutwell, eds. Carcinogenesis - A Comprehensive Survey-Volume 2, Raven Press, New York, N.Y., 443-448, (1978).

22. Pitot, H.C., *et al.*, "Stages in the Process of Hepatocarcinogenesis in Rat Liver", in T.J. Slaga, A. Sivak, R.K. Boutwell eds. Carcinogenesis - A Comprehensive Survey - Volume 2, Raven Press, New York, N.Y., 433-442, (1978).

23. Goerttler, K., *et al.*, "Systemic Two-State Carcinogenesis in the Epithelium of the Forestomach of Mice Using 7, 12-dimethylbenz (a) anthracene as Initiator and the Phorbolester 12-O-tetradecanoyl-phorbol-13-acetate as Promoter," Cancer Res. 39, 1293-1297, (1979).

References, cont'd....

24. Witschi, H. & Lock, S., "Butylated Hydroxytoluene: A Possible Promoter of Adenoma Formation in Mouse Lung," In T.J. Slaga, A. Sivak, R.K. Boutwell, eds. Carcinogenesis - A Comprehensive Survey - Volume 2, Raven, Press, New York, N.Y., 465-474, (1978).

25. Wynder, E.L., "Tumor Promotion and Cocarcinogenesis as Related to Man and His Environment," In T.J. Slaga, A. Sivak, R.K. Boutwell, eds., Carcinogenesis - A Comprehensive Survey - Volume 2, Raven Press, New York, N.Y., 59-78, (1978).

26. Pound, A.W., "Influence of Carbon Tetrachloride on Induction of Tumors of the Liver and Kidneys in Mice by Nitrosamines," BR. J. Cancer 37, 67-75, (1978).

27. Narisawa, T., et al., "Promoting Effect of Bile Acids on Colon Carcinogenesis after Intrarectal Instillation of N-methyl-N'-nitro-N-nitroso-guanidine in Rats," J. Natl. Cancer Inst. 53, 1093-1097, (1974).

28. Pollard, M. & Luckert, P.H., "Promotional Effect of Sodium Barbiturate on Intestinal Tumors Induced in Rats by Dimethylhydrazine," J. Natl. Cancer Inst. 63, 1089-1092, (1979).

29. Reddy, B.S. et al., "Promoting Effect of Sodium Deoxycholate on Colon Adenocarcinomas in Germfree Rats," J. Natl. Cancer Inst. 56, 441-442, (1976).

30. Reddy, B.S., et al., "Colon Cancer: Bile Salts as Tumor Promoters," In T.J. Slaga, A. Sivak, R.K. Boutwell, eds. Carcinogenesis - A Comprehensive Survey - Volume 2, Raven Press, New York, N.Y., 453-464, (1978).

31. Weymouth, L.A. & Loeb, L.A. "Mutagenesis During In Vitro DNA Synthesis," Proc. Nat. Acad. Sci. 75, 1924-1928, (1978).

32. Berman, J.J., et al., "Enhancement of Mutagenesis During Cell Replication of Cultured Liver Epithelial Cells," Cancer Lett. 4, 277-283, (1978).

33. Maher, V. et al., "DNA Exclusion-Repair Processes in Human Cells Can Eliminate the Cytotoxic and Mutagenic Consequences of Ultraviolet Irradiation," Mutat. Res. 62, 311-323, (1979).

34. Laroye, G.J., "How Efficient is Immunologic Surveillance Against Cancer and Why Does it Fail," Lancet 1097-1100, (1974).

35. Peraino, C., et al., "Enhancement of Spontaneous Hepatic Tumorigenesis in C3H Mice by Dietary Phenobarbital," J. Natl. Cancer Inst. 51, 1349-1350, (1973).

References, cont'd....

36. Rossi, L. *el al.*, "Long-Term Administration of DDT or Phenobarbital-N in Wistar Rats," *Int. J. Cancer* *19*, 179-185, (1977).

37. Schumann, A.M., *et al.*, "The Pharmacokinetics and Macromolecular Interactions of Perchloroethylene in Mice and Rats as Related to Oncogenicity," *Toxicol. Appl. Pharmacol.* *55*, 207-219, (1980).

38. Griem, H., *et al.*, "Mutagenicity In Vitro and Potential Carcinogenicity of Chlorinated Ethylenes as a Function of Metabolic Oxirane Formation," *Biochem. Pharmacol.* *24*, 2013-2017, (1975).

39. Bartsch, H., *et al.*, "Mutagenic and Alkylating Metabolites of Haloethylenes, Chlorobutadienes and Dichlorobutenes by Rodent or Human Liver Tissues," *Arch. Toxicol.* *41*, 249-277, (1979).

40. Weisburger, J.H., *et al.*, "Modification of Diethylnitrosamine Liver Carcinogenesis with Phenobarbital but not with Immunosuppression," *J. Natl. Cancer Inst.*, *54*, 1185-1188, (1975).

41. McLean, A.E.M., *et al.*, "Reduced Carcinogenic Effects of Aflatoxin in Rats Given Phenobarbitone," *Br. J. Exp. Pathol.* *52*, 322-329, (1971).

42. Peraino, D., *et al.*, "Reduction and Enhancement by Phenobarbital of Hepatocarcinogenesis Induced in the Rat by 2-Acetylaminofluorene," *Cancer Res.* *31*, 1506-1512, (1971).

43. Berenblum, I. & Armuth, V. "Two Independent Aspects of Tumor Promotion" *Biochim. Biophys. Acta* *651*, 51 (1981) ("the multi-stage theory [of carcinogenicity involving an initiation and promotion mechanism] is now generally accepted, though the precise nature of the component stages is, to a limited extent, still a matter of controversy"); Miller, E. & Miller, J. "Mechanisms of Chemical Carcinogenesis" *Cancer* *47*, 1056 (Mar. 1 Supplement, 1981) ("carcinogenesis is now generally recognized as a multistage process" involving initiation and promotion); *Food Chem. News* *23*, 34-39 (Feb.22, 1982) (description of consensus at recent Toxicology Forum meeting recognizing that different mechanisms are involved in carcinogenicity).

44. Weisburger, J.H. & Williams, G., "The Decision-Point Approach for Systematic Carcinogen Testing" *Food Cosmet. Toxicol.* *19*, 561, (1981); Williams, G., "Liver Carcinogenesis: The Role for Some Chemicals of an Epigenetic Mechanism of Liver-Tumor Promotion Involving Modification of the Cell Membrane", *Food Cosmet. Toxicol.* *19*, 577, (1981).

References, cont'd....

45. Anon., *Food Chem. News 23*, at 37, (Feb. 22, 1982).

46. Squire, Robert A., "Human Risk Assessment from Animal Data,: Paper Delivered at American Chemical Society Symposium on Pesticide Chemist and Modern Toxicology, (June 1980).

47. Watanabe, P., Reitz, R. *et al*., "Implications of the Mechanisms of Tumorigenicity for Risk Assessment" in Witschi, H. (ed.) *The Scientific Basis of Toxicity Assessment* at 76, (1980) ("Understanding the mechanism of tumor formation is critical in assessing the risk of exposure because different protective measures are indicated depending on whether the predominant mechanism is genetic or epigenetic.")

48. Maslansky, C. & Williams, G., "Evidence for an Epigenetic Mode of Action Organochlorine Pesticide Hepatocarcinogenicity: A Lack of Genotoxicity in Rat, Mouse, and Hamster Hepatocytes", *J. of Toxicol. Environ. Health 8*, 121, (1981); Williams, G. "Liver Carcinogenesis: The Role for Some Chemicals of an Epigenetic Mechanism of Liver-Tumors Promotion Involving Medication of the Cell Membrane: *Food Cosmet. Toxicol. 19*, 577, (1981); Weisburger, J.H. & Williams, G., "Chemical Carcinogens: in Doull, Klaasen & Amdur (eds). *Casarett and Doull's Toxicology* at 133, (1980).

49. Stott, W. & Watanabe, P., "Differentiation of Genetic Versus Epigenetic Mechanisms of Toxicity and its Application to Risk Assessment" *Drug Metab. Rev.* (1982) (in press). This article also states that, in terms of human risk, the kind of exposure usually necessary for an epigenetic substance to invoke a carcinogenetic response is "not likely [to be] found either occupationally or in the environment."

50. Weisburger, J.H., & Williams, G., "Carcinogen Testing: Current Problems and New Approaches", *Science 214*, 406, (1981).

51. Ramsey, J.C. Park, C.M., Ott, M.G., & Gehring, P.J., "Carcingoenic Risk Assessment: Ethylene Dichloride", *Toxicol. Appl. Pharmacol. 47*, 411-414, (1979).

52. Cordle, F., "The Use of Epidemiology in the Regulation of Dioxins in the Food Supply", *Regul. Toxicol. Pharmacol. 1*, 379-387, (1981).

53. "The Evaluation of the Carcinogenicity of Chemical Substances", Report submitted by a Committee of the Health Council of The Netherlands, 1980.

References, cont'd....

54. Upton, A.C., "Preventive Medicine in the Workplace: Prospects for the 1980s", *J. Occup. Med.* *23*, 556-560, (1981).

55. Fishbein, L., *"Potential Industrial Carcinogens and Mutagens, (Studies in Environmental Science; 4)"*, Elsevier, Amsterdam, at 4 (1979).

56. Cowan, M.D., letter to Donald Millar, director of the National Institute of Occupational Health and Safety, quoted in *Science* *217*, 884, (1982).

GLOSSARY OF ABBREVIATIONS

ACGIH	American Conference of Governmental Industrial Hygienists
DNA	Deoxyribonucleic Acid
EEC	European Economic Community
EPA	Environmental Protection Agency (U.S.)
FDA	Food and Drug Administration (U.S.)
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act (U.S.)
GRAS	Generally Recognized As Safe
NTA	Nitrilotriacetic Acid
OECD	Organization for Economic Cooperation and Development
RNA	Ribonucleic Acid
TLV	Threshold Limit Value
TSCA	Toxic Substances Control Act (U.S.)
TWA	Time-Weighted Average
WHO	World Health Organization

APPENDIX

QUANTITATIVE RISK ASSESSMENT: STATE-OF-THE-ART FOR CARCINOGENESIS

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ABSTRACT

A critical evaluation of the use of statistical models in carcinogenic risk assessment is made with emphasis on the strengths and weaknesses of current practice. The objective is to bring together information from the fields of toxicology and statistics to develop a sound scientific basis for making risk decisions. It is emphasized that risk assessment is a complex, multifaceted process that is not easily quantified and, at present, must be based on qualitative as well as quantitative information. It is evident that dose-response modeling of tumor incidence data from animal studies is of limited value in estimating human risk associated with low-dose chemical exposures. The models take into account only one part of the complex process and have no accepted basis in biology. The key decision points, qualitative factors, and quantitative considerations are identified and discussed and a risk assessment framework that incorporates these inputs is presented for consideration. It is concluded that much work needs to be done before a completely quantitative approach to risk assessment is to be useful; in particular pharmacokinetic modeling should be pursued more aggressively.

TABLE OF CONTENTS

Page

1. INTRODUCTION 197
   - 1.1 Risk Assessment Process 198
   - 1.2 Some Views of the Current State-of-the-Art 199
2. MODELS USED IN RISK ASSESSMENT 201
   - 2.1 Mechanistic Models 202
   - 2.2 Tolerance Distribution Models 206
   - 2.3 Other Useful Models 208
3. LIMITATIONS OF THE MODELS
   - 3.1 Incorporating Qualitative Information 209
   - 3.2 Extrapolation of Quantal Data 213
4. STATISTICAL MODELING PROCEDURE IS INCOMPLETE 215
   - 4.1 Results of Negative Studies Should not be Ignored 215
   - 4.2 Using All the Data to Estimate Potential Risk 216
5. BEST ESTIMATES AND CONFIDENCE LIMITS SHOULD BE REPORTED 217
6. ALTERNATIVE ANALYSES OF CHRONIC STUDIES 217
   - 6.1 Estimation of No-Observed-Effect-Levels 218
   - 6.2 Comparison of Dose-Response Curves 219
   - 6.3 Time-to-Tumor Data Should be Included 220
7. TOWARD A REALISTIC RISK ASSESSMENT PROCEDURE 221
   - 7.1 Key Aspects of Risk Assessment 221
   - 7.2 A Conceptual Model for Risk Assessment and Management 225
8. SUMMARY AND CONCLUSIONS 230
9. REFERENCES 232

QUANTITATIVE RISK ASSESSMENT: STATE-OF-THE-ART FOR CARCINOGENESIS

1. INTRODUCTION

Society has made extensive use of chemicals to improve our standard of living. This use has resulted in a need to determine the risks associated with exposure to man-made and natural chemicals. Much discussion and disagreement on the subject of carcinogenic risk assessment and management has focused on the use of mathematical models for estimating potential risks. The purpose of this paper is to evaluate the current state-of-the-art of quantitative risk assessment, identify strengths and weaknesses of current methodologies, and provide an alternative procedure to stimulate discussion on this important subject.

It is important to recognize that risk assessment encompasses three key areas: hazard identification, hazard evaluation, and risk evaluation (Figure 1, AIHC 1981). After a potential hazard has been identified, a hazard evaluation is made to determine from experimental data what kind of human responses could be expected under laboratory exposure conditions. The output of the hazard evaluation includes an estimate of the potential risk to humans. Since a hazard is not a risk to humans until there is exposure, a risk evaluation is made to determine whether and to what extent the potential hazard of a substance is realized in the real world. Risk evaluation combines the results of the hazard evaluation with information about the route and extent of exposure and number of persons exposed to estimate the extent of the risk to society.

Mathematical models have been widely used in the hazard evaluation step of risk assessment to estimate potential risk to humans from exposure to chemicals. It is, unfortunately, often assumed that risk assessment relies totally on mathematical models. This impression is partially due to the considerable discussion and controversy surrounding the use of mathematical approaches, as well as the fact that models have been over emphasized to the point of the exclusion of many important qualitative and quantitative factors necessary for the rational evaluation of risk. Quantification of potential risk and numerical determination of permissible exposure limits are often desirable but, as we will discuss, risk assessment must also incorporate a number of qualitative factors.

Risk management is the decision process that evaluates the benefits of the chemical versus the risks, costs, and alternatives. It includes the regulatory response made to assessed risk (Figure 1). The result is the determination of how a given chemical can be safely manufactured, transported, used, and disposed of with no significant impact on human health and the environment.

By its very nature, risk assessment is mainly a scientific activity while risk management is principally a political activity (Figure 1). The focus of this paper is on risk assessment for we believe that sound risk management decisions will only result if a sound scientific analysis of the problem and data is made. It is important to keep these two activities separate because to do otherwise creates confusion and reduces the effectiveness of risk assessment and management.

1.1 Risk Assessment Process

Carcinogenic risk assessment is a complicated process that includes an analysis of the following types of studies in order to evaluate hazards and estimate the associated risks to humans (Figure 2).

- Mutagenicity
- Acute studies in animals
- Subchronic studies in animals
- Metabolism
- Chronic studies in animals
- Epidemiology
- Route and amount of exposure

When these different types of data are organized, analyzed, and collectively interpreted, an understanding of the toxic potential of the chemical appears. Only after such an exercise has been conducted, do we have the scientific knowledge to decide how to handle a chemical. At present, formalized statistical models have been developed only for chronic carcinogenic studies in animals. Models that combine data from the other types of studies have not been developed and likely will not be used in the near future.

The interest in evaluating the potential hazard of human exposures of many orders of magnitude below the experimental data base has led to the use of mathematical extrapolation models for predicting potential risk due to low-dose exposure. It was hoped that these models could characterize the low end of the dose-response curve for risk in laboratory animals and that the estimated dose-response would be useful for estimating human risk. Risk assessment by necessity, however, involves a number of qualitative decision points that are a very important part of the process and must not be overshadowed by the numerical aspects of risk assessment.

For instance, some compounds produce tumors early in life, at multiple sites and at doses with no other apparent toxicological response. In contrast, other chemicals produce a tumorigenic response only after overwhelming doses, very late in life, and often only at a single site where associated nontumorigenic toxicity is evident. These qualitative differences are important in assessing the potential for human hazard but they are not considered in the currently used mathematical models.

1.2 Some Views of the Current State-of-the-Art

There has been considerable discussion on the use of models in risk assessment and the biological basis for the models. Critics of a rigid modeling approach emphasize that results of chronic studies represent only part of the data base and that the biological processes are extremely complex. Squire (1981b) points out that

> "no models can actually be based on the biological events, since these are not known for any carcinogens."

This disparity between biological reality and the relevance of models has led to disagreement on the usefulness of the mathematical approach. It is generally agreed that a model must be based on fundamental biological mechanisms in order for its predictions outside the range of the observed data (ie, extrapolations) to be of any value.

Carter (1979) reports that

> "Disagreement exists within the government itself over 'cancer policy' and especially over whether the science of quantifying cancer risks is far enough advanced for it to be safely used by regulatory agencies in setting standards for human exposure to carcinogens."

The National Academy of Sciences Committee that reviewed the pesticides regulation process (NAS 1980) studied the use of statistical models for describing results from limited bioassay data and reported

> "The Committee scrutinized carefully the methods used by OPP and EPA's Carcinogen Assessment Group. As a result of this scrutiny it came to the conclusion, very much in line with the position of the Director of the NCI (Carter 1979), that our present understanding of the mechanisms of cancer development does not permit us to draw reliable numerical inferences from the kind of laboratory data normally available about the effects of pesticides and other compounds on the development of cancers in humans."

Munro and Krewski (1981) commented in their review of risk assessment and regulatory decision making that

> "The use of point estimates of risk as a major decision criterion in the regulatory control of carcinogens would permit an assessment of the relative risks due to various compounds. Although this perhaps represents the ultimate application of mathematical modeling techniques, knowledge deficiencies in the science base presently preclude the possibility of realizing the full potential of the available procedures at this time."

Wahrendorf (1979) in an editorial on the estimation of safe dose levels concludes

> "The problem of safe dose estimation will definitely not be solved by the application of different mathematical dose-response models and the relevant statistical techniques of extrapolation alone. One should keep in mind that the isolated investigation of a noxa in a relatively homogeneous population of experimental animals, where the conditions are kept constant, is far removed from the situation of man in his environment."

These are only a few of the several instances in which scientists have expressed reservations concerning the use of potential risks calculated by statistical models. This does not mean that models should not be used. There are many cases in which it is necessary to arrive at permissible exposure limits and these estimates must be derived from existing quantitative data. The derivation of quantitative estimates from a quantitative data base implies the existence of a model, regardless of whether it is a simplistic model such as a safety factor or a more sophisticated approach. Modeling in one form or another will be used. It is important, however, to recognize the limitations and assumptions involved, and not to bury biological judgments in mathematical sophistication. A major concern is that no amount of disclaimer by the risk assessor will necessarily keep the risk manager from interpreting risk estimates at face value.

The strengths and weaknesses of currently available methodology do not seem to be well understood. The intent of this document is to summarize the state-of-the-art, bring together information from toxicology and statistics, and provide direction for future work. Box (1979) has emphasized that "all models are wrong but some are useful." All models are wrong because we never know the true state of nature. The relevant concern, therefore, is whether the model is illuminating and useful. We encourage our readers to keep this perspective in mind as they evaluate the use of models in risk assessment.

2. MODELS USED IN RISK ASSESSMENT

The models commonly used in risk assessment are based on either mechanistic or tolerance distribution assumptions.

Mechanistic Models	Tolerance Distribution Models
One-hit	Probit
Multistage	Logit
Multi-hit	Weibull

The use and assumptions of these models have been discussed in detail elsewhere (Bruce 1980, Brown 1978, Food and Safety Council 1980, Krewski and Brown 1981) and will be reviewed only briefly here. Pharmacokinetic modeling, which is also a mechanistic approach, is discussed separately in Section 2.3.

We should keep in mind that, while these models frequently fit the observed data equally well, they can predict very different potential risks at low doses. Krewski and Van Ryzin (1981) have shown mathematically, and by example, that the models tend to have the following relationship to each other at low doses:

Model	Estimate of Potential Risk
One-hit	Highest
Linear	
Multistage	
Weibull	
Multi-hit	
Logit	
Probit	Lowest

The statistical approach to selecting the best model would be to design the bioassay to discriminate among these models and identify the most useful candidate model(s). Unfortunately, as Crump (1982) points out, it may not be possible to design such experiments. Clearly, the models disagree most in the low-dose region where the data contain no information (ie, no excess tumors are observed). A brief description of some of the commonly used models is given in the following sections.

2.1 Mechanistic Models

One class of mechanistic models is derived from assumptions about the age specific tumorigenicity rate which is the frequency of people developing tumors in a given age group. If the age specific tumor rate (r) is a function of dose and age,

$$r = f\ (\text{dose}, \text{age})$$

and if the dose and age components can be separated into two mathematical functions so that

$$f(\text{dose}, \text{age}) = g(\text{dose})\ h(\text{age}),$$

then the cumulative lifetime risk for a given dose is found by integrating over age. The resulting class of models is

$$P = 1 - \exp\ (-g(\text{dose})),$$

where P is the probability of tumor and g(dose) is a mathematical function of dose.

One-Hit Model

This family of distributions includes the one-hit model for which

$$g(\text{dose}) = b_1(\text{dose})$$

and b_1 is a parameter to be estimated from data. This functional form assumes that for any given age, the probability of a tumor is directly proportional to the amount of exposure. This can result from the assumption that only one critical molecular event between a target site and the proximate carcinogen is sufficient to result in a tumor, and the probability of such an interaction is directly proportional to the nominal concentration of the carcinogen. This mechanism is, however, not the only one that is consistent with this equation.

The one-hit model and variations on it utilizing upper statistical limits (Gaylor and Kodell 1980) represent a highly conservative approach to the extrapolation problem (Hoel 1981). For example, a linear extrapolation of the Chemical Industries Institute for Toxicology formaldehyde study predicted that an average lifetime dose less than 0.66×10^{-3} ppm was needed to keep the lifetime potential risk of tumor less than 10^{-6} (Gibson 1982). Such an estimate has little credibility as an estimate of the risk to humans when viewed in light of some 100 years of experience with human exposures to formaldehyde which generally are less then 0.1 ppm but have often been in the 0.1 to 5 ppm range (Todhunter 1982) with no apparent increased carcinogenic risk.

The one-hit model assumes a dose-response that is approximately linear at low doses and concave downward over the entire dose range. The model, as commonly used, ignores the toxicological reality of nonlinear dose-response mechanisms, saturation kinetics, no effect levels or thresholds of a real or practical nature.[1] The one-hit model is, however, relatively insensitive to minor fluctuations in the data. It should be noted that linear extrapolation from the lowest observed effect level to a potential risk of 10^{-6} (one in a million) generally results in a safety factor of approximately 100,000. Assuming an observed response level of 10 percent which is about the lowest detectable effect level in a standard bioassay, the safety factor = response/desired potential risk = $0.10/10^{-6}$ = 100,000. This indicates that the dose corresponding to a potential risk of 10^{-6} is approximately 1/100,000 of the lowest practically observable effect level.

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[1] We define a practical threshold as a dose so low that the probability of any tumors in the lifetime of a given population is negligible.

The dose-response curve calculated from the one-hit model is essentially independent of the shape of the observed dose-response curve, gives very little weight to no-observed-effect-levels (NOEL), and may not be predictive of potential risk at low levels. When good epidemiology data are available for comparison, it has in some cases been found that the one-hit model is not compatible with the human experience (Gehring, Watanabe, and Park 1979; Ramsey, Park, Ott, and Gehring 1979; Reitz, Gehring, and Park 1978). Carlborg (1981a) concluded that the one-hit model did not give an adequate fit to most of the 31 data sets he analyzed. The one-hit model also does not fit the data obtained in the ED_{01} Study conducted by National Center for Toxicological Research (Carlborg 1981b). This study used over 24,000 mice and was designed to define the shape of the dose-response curve at the low end, near 1 percent.

With appropriate species conversion, the one-hit model does, however, estimate an upper limit on the potential risk and may be useful in situations where an upper bound is of interest. For example, if the potential risk calculated by the one-hit model is not unacceptable, then there would be less need to consider other models. On the other hand, if permissible exposures predicted by the one-hit model are unrealistically low, which is often the case, then further risk analyses would have to be made to confirm or refute the one-hit model results. In all cases we must keep in mind that potential risks predicted by the one-hit model may be several orders of magnitude more than that of the true potential risk (factor of 10 = one order of magnitude).

Multistage Model

The multistage model assumes

$$g(\text{dose}) = (a_1+b_1\text{dose})(a_2+b_2\text{dose}) \ldots (a_n+b_n\text{dose})$$
$$= c_0 + c_1\text{dose} + c_2\text{dose}^2 + \ldots + c_n\text{dose}^n,$$

where a_i, b_i, $c_i \geq 0$ are parameters that vary from chemical to chemical. The biological justification for this model is that cancer is believed to be a multistage process that can be approximated by a series of multiplicative linear functions (a_i + $b_i$dose). This model is likely to be conceptually useful in some cases. In a theoretical sense, for instance, the concentration of the proximate carcinogen at the target site can be modeled by a series of kinetic reactions that are usually assumed to be linear at low doses but may be saturable (nonlinear) at high doses. Concentration kinetics may be linear at low doses. This does not necessarily imply a proportional response because at some concentration the existence of defense and repair systems is likely to modulate the response.

In practice, however, this results in fitting a polynomial model to the dose-response curve. The function generally fits well in the experimental dose range but has very limited applicability to the estimation of potential risk at low doses. The limitations arise first because the model cannot reflect changes in kinetics, metabolism, and mechanisms at low doses; and second because low dose estimates are highly sensitive to a change of even a few observed tumors at the lowest experimental dose.

A logical statistical approach to account for the random variation in tumor frequencies is to express the results in terms of best estimates and measures of uncertainty. The following model provides an upper confidence limit on the potential risk but does not give a best estimate.

"Linearized" Multistage Model

The "linearized" multistage model proposed by Crump (1981) and utilized by many of the regulatory agencies replaces the linear term (b_1) of the polynomial function, g(dose), by its upper 95 percent confidence limit to reflect biological variability in the observed tumor frequencies. The dose-response predicted by this model is approximately linear at low doses (the d^2, d^3, etc, terms are essentially zero at low doses) resulting in estimates of potential risk that are almost identical to those of the one-hit model. Even for extremely nonlinear data (eg, nitrilotriacetic acid, Food and Safety Council Report 1980) estimated doses corresponding to potential risk levels of 10^{-6} differ only by less than a factor of 6 from the estimate of a one-hit model extrapolation. Thus, for almost all applications there is no appreciable difference between the linear model and the linearized multistage model.

This modeling approach relies totally on the upper confidence level for b_1 and ignores the best estimate of b_1 as well as the lower confidence limit. The result is that the model can produce a very high estimate of potential risk even when the dose-response function is very steep and when the exposure levels are well below no-observed-effect-levels.

The model has the potential to be applied even when the total dose-response is not statistically significant. We believe, however, that this can be very misleading and that low-dose extrapolation models should be used only when a statistically significant dose-response has been established.

Multi-Hit Model

The multi-hit model has been discussed in some detail in the Food Safety Council Report (1980). One derivation of this model follows from the assumption that K "hits" or molecular interactions are necessary to induce the formation of a tumor and the distribution of these molecular events over time follows a Poisson process. In practice the model appears to fit some data sets reasonably well and to give low dose predictions that are similar to the other models. There are cases, however, in which the predicted values are inconsistent with the predictions of other models by many orders of magnitude. For instance, the virtually safe dose (VSD) for nitrilotriacetic acid as predicted by the multi-hit model is much higher than that predicted by other models. In the case of vinyl chloride the multi-hit model predicts a much lower VSD than other models (Food Safety Council Report 1980).

2.2 Tolerance Distribution Models

Another approach to the modeling problem is to assume that each member of the population will develop a tumor if exposure to the carcinogen exceeds a critical level. This threshold level varies from individual to individual and has been modeled by various tolerance distributions.

Log-Probit Model

The log-probit model assumes that the individual tolerances follow a lognormal distribution. Specific steps in the complex chain of events that lead to carcinogenesis are likely to have lognormal distributions. For example, it is reasonable to assume that the distribution of a population of kinetic rate constants for detoxification, metabolism, elimination, as well as the distribution of immuno-suppression surveillance capacity and DNA repair capacity can be adequately approximated by normal or lognormal distributions.

Tolerance distribution models have been found to adequately model many types of biological dose-response data, but it is an overly simplistic expectation to represent the entire carcinogenic process by one tolerance distribution. A tolerance distribution model may give a good description of the observed data but from a mechanistic point of view there is no reason to expect extrapolation to be valid. The probit model extrapolation has, however, fit well in some instances (Gehring, Watanabe, and Park 1979).

Logit and Weibull Models

Other tolerance distributions which have been used to model carcinogenicity dose-response data include the logit and Weibull models (Doll 1971, Carlborg 1981a). The multi-hit model discussed earlier can also be viewed as a member of this class of models that uses the gamma function to model the tolerance distribution. For this reason it is often called the gamma-multi-hit model.

The log-probit, logit, Weibull, and gamma distributions all have potentially similar shapes between tumor frequencies of 2 percent to 98 percent; hence, it is not surprising that these models often give essentially identical fits to the observed data, but again, the models differ widely at low doses.

2.3 Other Useful Models

Log-Linear Model

The log-linear model assumes the dose-response relationship

$$\text{Response} = B_1 \qquad \text{if dose} < d^*$$
$$\text{Response} = B_1 + B_2 \log(\text{dose}/d^*) \qquad \text{if dose} \geq d^*$$

and incorporates a parameter d* that represents a threshold below which no dose-related response occurs. In this model B_1 is the response level at doses less than d* and B_2 is the slope of the logdose-response curve at doses ≥ d*. It has been empirically found that many quantitative toxicological end points can be adequately described by the log-linear model. This model may, therefore, be useful for establishing thresholds for end points related to the carcinogenic process in situations where information other than the simple presence or absence of a tumor is available. Both the model and predicted threshold are of value when carcinogenicity is a secondary event. The use of this model in estimating no-observed-effect-levels is discussed further in Section 6.1.

Pharmacokinetic Models

Pharmacokinetic models have often been used to predict the concentration of the parent compound and metabolites in the blood and at reactive sites, if identifiable. Cornfield (1977), Gehring and Blau (1977), and Anderson, Hoel, and Kaplan (1980) have extended this concept to include rates for macromolecular events (eg, DNA damage and repair) involved in the carcinogenic process. The addition of statistical distributions for the rate parameters and a stochastic component representing the probabilistic nature of molecular events and selection processes may represent a useful conceptual framework for describing the tumorigenic mechanism of many chemicals. Pharmacokinetic data are presently useful only in specific parts of the risk assessment process. A more complete understanding of mechanism of chemically induced carcinogenesis would allow a more complete utilization of pharmacokinetic data. Pharmacokinetic comparisons between animals and humans are presently most useful for making species conversions and understanding the qualitative and quantitative species differences. The modeling of blood concentrations and metabolite concentrations identifies the existence of saturated pathways and adds to the understanding of the mechanism of toxicity in many cases.

In the future as more is understood about the mechanisms of carcinogenesis, formalized quantitative approaches incorporating pharmacokinetic data will likely become more useful in risk assessment.

3. LIMITATIONS OF THE MODELS

The models described above, with the exception of pharmacokinetic approaches, are generally an oversimplification of a complex system and apply only to the chronic animal toxicity studies that are but one input to the risk assessment process. The models have little biological relevance, have been shown to provide poor extrapolation estimates and, with a few exceptions, have not been validated either in animals or with respect to the human experience. Many of these models can be used, however, to summarize the dose-response curve within the range of observable responses and pharmacokinetic models are of use for understanding and predicting specific parts of the overall process.

Two major problems with the use of formalized modeling approaches are, 1) the inability of models to incorporate much of the qualitative information that must be used to arrive at logical decisions, and 2) the statistical problems involved in extrapolating quantal data.

3.1 Incorporating Qualitative Information

The importance of the qualitative decisions is evidenced in the process by which both governmental agencies and industry determine how to handle a potential carcinogen. It is initially a two-step procedure in which a qualitative decision is made as to whether the compound is an animal and/or potential human carcinogen. If the answer to either of these questions is yes, then the risks to humans are estimated and a decision is made as to how to handle the compound. If a complete risk estimation model existed, there would be no need for the first step. The model would be used to compute the risks directly and noncarcinogens would be assigned very small or zero risks.

Unfortunately, our current state of knowledge does not permit us to take this approach.

Type of Tumor is Important

There are many specific qualitative decision points that impact the quantitative estimation of potential risk. These qualitative data include the type of tumor observed in the experimental animal. The B6C3F1 mouse, for example, is highly sensitive to hepatic tumors and the majority of male Fischer 344 rats develop testicular tumors independent of any chemical exposure. Chemicals that increase the incidence of these tumors but do not show any other tumorigenic activity should be considered as possible promoters of tumorigenesis. Such chemicals are considered to be much less likely to cause human cancer than a potential carcinogen that produces a spectrum of histogenically different tumors including those with low spontaneous rates. The mechanisms of action for some promoters is entirely different from that of complete carcinogens and certain steps in the assessment of risk should reflect the different mechanisms.

Examples of chemicals that only increase the spontaneous liver tumor rate for B6C3F1 mice after chronic high exposures, and are apparently not carcinogenic in rats, and do not appear to be mutagenic or genotoxic include the chlorinated solvents, perchloroethylene, and trichloroethylene. These substances do not appear to present a significant carcinogenic risk to humans at present exposure levels.

Relevance of Tumor Type

A similar type of qualitative information that impacts estimates of potential risk is the relevance of the observed tumors in animals to potential human hazard. Examples of tumors that have limited predictability to humans from the animal model include zymbal gland carcinomas and tumors of the nasal turbinate. An excellent example is formaldehyde which produces tumors apparently only in conjunction with chronic irritation of the nasal passageways. The rat, as an obligatory nasal breather, is sensitive to chronic irritation of the nasal mucosa and develops tumors in this area after chronic exposure to a number of chemicals. While it is possible, of course, that excess human exposure would result in respiratory tumors, models used to estimate potential risk must be capable of appropriately incorporating this qualitative observation. Mathematical models currently in use do not have this capability.

Genotoxic and Nongenotoxic Mechanisms

Probably the most important qualitative difference between animal carcinogens is the distinction between carcinogens that operate primarily through direct genotoxic mechanisms and those that produce tumors through mechanisms other than direct interaction with DNA (ie, epigenetic, nongenotoxic, or nongenetic mechanisms). The subject of tumorigenic mechanisms has received a great deal of discussion (Weisburger and Williams 1980, Stott, et al 1981). Briefly stated, some chemicals that are carcinogenic in animals also interact directly with DNA as indicated by results of short-term in vitro tests, or by direct measurement of in vivo DNA alkylation and repair rates. Other chemicals that are tumorigenic in animals show virtually no activity in the genotoxicity tests and show no propensity to bind or interact with DNA. Research on some of these chemicals (eg, saccharin, chloroform, trichloroethylene, and perchloroethylene) has shown that, there is little to no direct interaction with DNA. On the other hand, in vivo tests indicate a dose-dependent acceleration in the rate of DNA synthesis at doses that correlate well with tumorigenicity and demonstrates an apparent tumorigenic mechanism and threshold.

In some of these cases the likely mechanism of action is cytotoxicity resulting in cellular regeneration accompanied by an increased rate of DNA synthesis. DNA is constantly undergoing a low background rate of damage and subsequent repair. If this background rate is increased (eg, when cellular damage necessitates an increase in the rate of DNA synthesis), the increased demands on the repair surveillance systems may lead to an increased probability of faulty DNA repair or the possibility of replication before repair is completed. This phenomenon can be demonstrated by the production of skin tumors following burns, repeated exposure to ultraviolet radiation, repeated freezing of the skin with dry ice, (Berenblum 1929, Laroye 1974) and liver tumors following partial hepatectomy.

Cytotoxicity and direct cellular damage leading to tumorigenesis is only one nongenotoxic mechanism for carcinogenesis. Weisburger and Williams (1980) point out that other nongenotoxic mechanisms and examples include solid state carcinogens (polymers, asbestos), hormonal imbalance carcinogens (estradiol, DES), immuno suppressors (azothioprine), and promoters (phorbol esters, saccharin).

Use of Mechanistic Information

The subject of tumorigenic mechanisms is extremely complex. For example, when classifying chemicals with respect to carcinogenic mechanisms, we should keep in mind that genotoxicity is a continuous spectrum rather than a dichotomous classification. Some chemicals clearly have a direct genotoxic component while others are at or near the nongenotoxic end of the scale. When doing risk assessment, it is important to identify those compounds that apparently operate through mechanisms other than direct genotoxicity. The importance of the distinction between genotoxic and nongenotoxic mechanisms is that, according to current theory, all that is needed for directly genotoxic chemicals to initiate a tumor is a single molecular event; thus, thresholds may not exist. We note, however, that the existence of protective mechanisms, such as DNA repair systems that are saturable, would imply the existence of a *practical* threshold.

On the other hand, for nongenotoxic mechanisms, more than a single molecular interaction is necessary to produce a tumor. The consensus of scientific opinion is that, for some of these mechanisms, as with other toxicologial phenomena, either an absolute threshold exists or the dose-response curve is so flat as to be indistinguishable from zero slope at low doses (ie, a practical threshold exists). In many cases, the existence of an observable precursor related to tumorigenicity (eg, cellular toxicity, necrosis, and hyperplasia), or a change in the rate of DNA synthesis provide a marker variable that can be used to predict the threshold below which the nongenotoxic mechanism ceases to pose a risk.

For instance, many chemicals increase the spontaneous rate of hepatic tumors in B6C3F1 mice. High doses of many of these compounds result in tumorigenicity that is often preceded in dose and in time by microscopically observable histological alterations. For these chemicals the experimentally observable tumor frequency data are often augmented by earlier quantitative signs of clinical and subclinical liver toxicity that can be most useful in establishing better measures of no-observed-effect-levels. In those cases, a practical threshold exists as well as a mechanism for observing and quantifying the threshold.

These chemicals should be viewed as promoters of tumorigenesis in animals and should be evaluated as such in the traditional manner of other quantitative toxicological phenomena with demonstrated no-effect levels. Knowledge of species differences in metabolism and all the accompanying scientific judgments should be used in estimating the corresponding safe level for humans.

3.2 Extrapolation of Quantal Data

Another major limitation of the models is the large statistical uncertainty in extrapolating data orders of magnitude below the observable range, particularly for quantal responses. Two sources of variation that contribute to the uncertainty inherent in tumor frequencies are statistical (binomial) variability which implies a large degree of variation in tumor counts and experiment-to-experiment variability.

Tumor Identification is Based on Subjective Judgment

We should also keep in mind that the variation observed in tumor frequency is a function of the uncertainty involved in classifying lesions into categories of "tumors" and "nontumors"; such as the subjective judgments used in separating high grade hyperplasia of the liver from low grade carcinomas. It was emphasized in the various examinations of data in the ED_{01} Study conducted by the National Center for Toxicological Research that the distinction between carcinomas and "nontumors" such as hyperplasia is a subjective judgment and may not be consistent from pathologist to pathologist (Squire 1981a). It is also important to recognize that this judgment is often most difficult to make at low doses because a dose-response may exist in the severity of lesion as well as the frequency of lesions. At high doses malignancy is often clearly defined; however, at low doses the responses are often equivocal and may be classified as tumors or nontumors, depending on the opinion of the pathologist.

Quantitative Measures of Carcinogenesis are Needed

A large source of statistical variability in the estimated potential risks is due to the inherent problem of extrapolating quantal responses. When information available on each animal is only the determination of presence or absence of a particular tumor, the standard error of the quantal estimate is large when compared to the standard error of quantitative measurements such as organ weights or clinical chemistries.

Recent theoretical work and simulation studies (Brown 1978, Krewski 1981) have shown that variation between models for the same data sets and variation in the estimates of potential risk produced by the same model as a result of random binomial variability can result in low-dose risk estimates varying by orders of magnitude. The problem of correctly specifying a model in the absence of biological mechanisms, combined with the inherent variability in low-dose extrapolation places severe limitation on the usefulness of a rigorous modeling approach. This is not to say that dose-response modeling should not be done; there are situations in which quantification is necessary and the information is useful for other than regulatory purposes. It is important, however, to understand the limitations of quantitative approaches so that computer generated estimates of potential risk are not given more credibility than they deserve.

Determination of the Dose to the Target Tissue is Critical

Another reason for the large uncertainty and inconsistency noted in the extrapolation process is the measurement of dose or exposure. The dose used in the modeling should be that which is seen by the target tissue rather than the nominal dose administered to the animal. This is especially important if the exposure route in the experiment is different from that of the human. If the nominal and effective doses are strictly proportional, then nominal dose is an appropriate surrogate. Often, however, the high doses used in a bioassay saturate normal detoxification and excretory mechanisms resulting in nonlinear relationships between nominal and effective doses. In this case, Michaelis-Menten kinetics are observed and may be accompanied by alternative metabolic and excretory pathways that can result in enhanced toxicity of the chemical (Gehring and Blau 1977). The overall consequence of nonlinear pharmacokinetics is that toxicity may increase disproportionately with increasing dose. Thus, extrapolation from high doses at which detoxification is overwhelmed to low nonsaturating doses using models that do not account for nonlinear kinetics can greatly overestimate the potential risk.

The issue becomes even more complicated when one relates the animal studies to humans and tries to determine the appropriate target tissue in humans and the dose of the chemical seen by those tissues. Metabolic and pharmacokinetic data can help answer these questions, but unfortunately, almost all dose-response modeling reported to date is based on doses administered to the animal with no regard for kinetic data (Anderson, Hoel, and Kaplan 1980).

4. STATISTICAL MODELING PROCEDURE IS INCOMPLETE

The statistical modeling procedure, as it is currently applied to the results of chronic studies, is incomplete because it does not account for differences in tumor site, adequacy and completeness of the study, sex, strain, or data regarding differences in species sensitivity. For example, a study of the effects of a chemical on 5 organs in male and female rats and mice in two laboratories would commonly result in $5 \times 2^3 = 40$ estimates of potential risk. Little critical thought has been given to summarizing this information into a single, or not more than a few, estimates; hence, a popular procedure has been to report the highest estimate. This sets a conservative upper bound on the true potential risk. There is a need, however, for more accurate estimates so that informed risk management decisions can be made.

4.1 Results of Negative Studies Should not be Ignored

It is often the case that for a particular chemical some studies show a positive tumorigenic response while others show no effect. These so-called "negative studies" may be due to the use of inadequate experimental designs, the result of small numbers of animals, or, as is often the case, may represent differences in species or strain sensitivities. As discussed in the next section, the results of negative studies can be combined with those of other studies to produce an overall estimate of potential risk that has higher precision than that of any of the individual studies. It is a fundamental principle of statistics that the average is a more precise estimate of an unknown true value than any subset of the measurements used to compute the average.

4.2 Using all the Data to Estimate Potential Risk

Quantal data on the frequency of observed tumors in groups of experimental animals provide only very limited statistical information. Thus, it is wasteful, as well as poor scientific practice, to use the study that gives the highest estimate of potential risk. This practice, along with ignoring negative studies and studies based on small sample sizes, has the potential to unnecessarily bias the results and will reduce the precision of the estimated potential risk. There are at least two ways to combine the results of chronic studies thereby increasing the precision of the risk estimate; 1) compute weighted averages of risk estimates and 2) use statistical models which allow for differences among data sets.

A generally accepted procedure for combining estimates from several studies is to compute a weighted average of the estimates. The weights commonly used are inversely proportional to the variances of the estimates. This approach uses all the data, incorporates the uncertainties associated with the data, and can be extended to include both within-study and between-study variance components (St. John, et al 1982).

Another approach to combining results from different sexes, studies, and strains is to incorporate parameters in the model to account for these differences (Carlborg 1981a). As described by Carlborg, chi-square tests are available to test for the appropriateness of this procedure. The result is models that utilize all the available information and produce more precise estimates of the potential risk at low-dose exposures.

5. BEST ESTIMATES AND CONFIDENCE LIMITS SHOULD BE REPORTED

Best estimates as well as lower and upper confidence limits should be routinely reported. The use of only the upper confidence limit on potential risk as the appropriate measure of risk is a political decision. When this is done, it results in political concerns and judgments becoming part of the risk assessment process which is inherently a scientific activity. The size of the confidence limits is inversely proportional to the quality of the data used to make the estimate and directly proportional to the amount of extrapolation involved. This important information is lost if the confidence limits and best estimates are not routinely reported. The width of the confidence interval is one of the best measures risk assessors and risk managers have to evaluate the quality of the estimates of potential risks. It is important to distinguish between those situations in which the risk is precisely estimated and those in which it is not.

As noted earlier, the use of only the upper confidence limit for the linear term (b_1) in the multistage model can result in a nonzero estimate of potential risk for a noncarcinogen. Reporting of the best estimate and both the lower and upper confidence limits for b_1 would alert the risk manager to the fact that the dose-response relation for the chemical was not statistically significant.

Confidence limits have some limitations that may not be well recognized. The confidence limits are statistically correct only if the model used to compute the limits is an accurate representation of the underlying dose-response function. Confidence limits do not provide a measure of modeling error; ie, the extent to which the model is correct. A measure of this uncertainty can be obtained, however, by fitting a number of different models including the calculation of their associated confidence limits (Hoel 1981).

6. ALTERNATIVE ANALYSES OF CHRONIC STUDIES

It should also be recognized that there are ways of evaluating the results of chronic studies other than fitting rigorous statistical models and extrapolating orders of magnitude away from the region of the data. Some of the more useful ways are: estimation of a no-observed-effect-level (NOEL), comparison of chemical dose-response to that of other chemicals, and use of time-to-tumor information. Each of these approaches is discussed in the following paragraphs.

6.1 Estimation of No-Observed-Effect-Levels

No-observed-effect-levels (NOEL) have been used by toxicologists for years to evaluate the potential risk due to exposure to chemicals. The use of NOEL's is often criticized because they are dependent on the number of animals tested at each dose level and the specific dose levels used in the experiment. The dependence on the dose levels tested is eliminated by fitting a statistical model that includes the NOEL as a parameter. The uncertainty of the estimated-no-observed-effect-level (E-NOEL) directly reflects the number of animals tested at each dose level. The E-NOEL is interpreted as the dose level at which no effect would have been observed if that dose level were tested in the study and if the model is correct.

In mathematical terms the E-NOEL could be estimated using the model

$$
\begin{aligned}
P &= B_1 && \text{if dose} < \text{NOEL} \\
P &= B_1 + F(\text{dose}) && \text{if dose} \geq \text{NOEL}
\end{aligned}
$$

where P is the probability of tumor, B_1 is the background, and F(dose) is the dose-response model used to describe the data. For example, in the case of a linear dose-response, the model would be

$$
\begin{aligned}
P &= B_1 && \text{if dose} < \text{NOEL} \\
P &= B_1 + B_2(\text{dose}-\text{NOEL}) && \text{if dose} \geq \text{NOEL}
\end{aligned}
$$

where NOEL is an unknown parameter whose estimate and uncertainty is determined by fitting the model to the data and B_2 is the slope of the dose-response curve for dose $\geq$ NOEL.

The dose-response data on bladder tumors in mice due to exposure to 2-acetylaminofluorene (2-AAF) is a good example where it is appropriate to consider the estimation of a NOEL (Figure 3, data obtained from Bruce, 1980). The logistic model

$$\ln(P/(1-P)) = -5.53 \qquad \text{if dose} < 56$$
$$\ln(P/(1-P)) = -5.53 + 6.75 \ln(\text{dose}/56) \qquad \text{if dose} \geq 56$$

was found to give an adequate fit to the data with an E-NOEL of 56 ppm and 95 percent confidence limits of 54 to 58 ppm. This analysis suggests that it is reasonable to consider an E-NOEL of between 54 and 58 ppm for 2-AAF. This, of course, does not prove the existence of a no-effect level between 54 and 58 ppm; rather, it implies that the data in the observable range are consistent with a logistic model and, under the assumption of the model, the dose-response curve reaches the observed background rate at a dose of between 54 and 58 ppm. As we will discuss in Section 7.2, this representation of the observed data may be a useful point of departure for determining a safe dose.

The existence of carcinogenic thresholds can, in general, neither be proved or disproved by the conventional bioassay; however, the concept of a threshold has worked well in the past for many toxicological responses. The E-NOEL and its uncertainty should be reported along with other estimates of potential risk whenever the model is shown to give an adequate fit to the data. Risk managers should be made aware when the existence of a theshold is consistent with the data.

6.2 Comparison of Dose-Response to That of Other Chemicals

The principal limitation of the virtually safe dose (ie, dose at which the estimated potential risk is small, eg, 10^{-6}) is that the VSD produced by current conservative methods are typically very far from the doses tested in the experiment and are extrapolations of empirical models. It may be appropriate to compare the observed dose-response with that of other chemicals to obtain a measure of relative potency. This can be done in several ways, each of which relates to the key features of the dose-response curve; 1) its location or distance from the origin and 2) its slope or steepness within the range of observable data.

There are at least two ways to do this. One is to plot a measure of the slope of the dose-response at its low end (eg, ED_{10}/ED_{01}, where ED_{01} and ED_{10} are the doses that are predicted by the model to produce 1 percent and 10 percent tumor rates) versus the E-NOEL discussed in Section 6.1. This plot would be limited to those situations where it was possible to obtain an E-NOEL.

Another possibility is a plot of the location and slope coefficients in a fitted model. In the case of the Weibull model,

$$P = 1 - Exp(A + B(dose)^M)$$

one would plot B versus M. Carlborg (1981a) has shown that this model, with background response, slope, and location parameters A, B, and M, respectively, can describe the dose-response of a wide variety of chemicals. This plot and the one mentioned in the previous paragraph could be used to compare the dose-response of "unknown chemicals" to the dose-response of chemicals whose carcinogenic potential is better known and understood.

One of the key advantages of these two approaches is that they allow both the risk analyst and risk manager to visually evaluate the available data and relate it to data on other chemicals rather than make a decision based on a computer generated estimate of potential risk that is typically orders of magnitude away from the data. It should be noted that these plots will be meaningful only if the dose of each chemical is expressed in the same units.

6.3 Time-to-Tumor Information Should be Included When Available

Recent analyses (Sielken 1981, Salsburg 1981, Van Ryzin 1981) of the ED_{01} study have pointed out that time-to-tumor information affects the shape of the dose-response curve, thereby influencing the estimates of potential risk produced by the models. It is recognized that in some instances accurate time-to-tumor information can be difficult to get without performing serial sacrifice experiments which may increase study costs. It is clear, however, that the determination of time-to-tumor is important in carcinogenicity studies and this information should be included quantitatively or qualitatively whenever possible.

The use of time-to-tumor data can also provide alternative measures of potential risk such as the "late risk dose" which is the dose corresponding to an acceptably late increase in risk and "mean free dose" which is a measure of the percent of lifetime free from tumor (Sielken 1981). These measures of potential risk are attractive because they are easy for people to understand. Further work is needed to better determine the utility of these approaches to risk modeling.

7. TOWARD A REALISTIC RISK ASSESSMENT PROCEDURE

The risk of developing cancer from chemical exposure cannot be estimated by a single number calculated by modeling the tumor incidence rates obtained in chronic studies. A number of different approaches is necessary. These will by necessity take into account several pieces of the risk assessment process (Figure 2) because an overall model is not available. The result will be a collection of qualitative and quantitative information that will be the basis for the final decision.

The following paragraphs first review proposals in the literature and then summarize the key decision points that are often not adequately considered in risk assessment. This discussion is followed by a quantitative risk assessment procedure that we present for consideration. The procedure incorporates the qualitative and quantitative data discussed in this paper and may be appropriate as a conceptual approach to risk assessment.

7.1 Key Aspects of Risk Assessment

Squire (1981b) includes the following types of data in his method for ranking animal carcinogens:

- Number of different species affected.
- Number of different types of neoplasms.
- Spontaneous tumor incidence in control groups.
- Dose-response relationships.
- Malignancy of induced neoplasms.
- Genotoxicity.

It is significant that, with the exception of dose-response relationships, these sources of information are not taken into account by any of the commonly used statistical models. Squire's ranking procedure considers only animal data. Human data should also be incorporated whenever they are available.

Weisburger and Williams (1981) also note the importance of understanding the mechanisms important to the carcinogenesis process and recommend an approach to carcinogen testing that is based heavily on the use of short-term tests *in vitro* to determine genotoxicity. Clearly, risk assessment must take genotoxicity into account but, unfortunately, the statistical models have not been extended to incorporate this critical information.

This paper has identified several qualitative factors and quantitative considerations that are critical to the risk assessment process. These are discussed below with particular reference to the type of data needed and the decision points involved. It is useful to collect these qualitative aspects into a "decision tree" framework such as in Figure 4. A decision tree requires clear-cut yes/no decisions that may be inappropriate for some of the factors being considered (eg, genotoxicity) but it is a useful concept for making some of the decisions required in risk assessment.

Qualitative Factors

Animal Carcinogenicity. The first decision is whether the compound is an animal carcinogen through any mechanism. This involves examining all the relevant animal studies and evaluating whether the data base indicates a treatment-related positive response in any species. The critical decision in this step is to avoid false positives and false negatives in making a valid judgment concerning the likelihood of a repeatable treatment-related response.

Potential for Human Carcinogenicity. This is an important step in the evaluation process that is often skipped. Many compounds have been shown to cause cancer in laboratory animals under specific conditions, but there are few proven human carcinogens possibly due to the lack of sensitivity of many epidemiology studies or the difference in human response at low exposures. Of course, the default assumption must be that humans will be similar to the appropriate animal model, but this does not imply an automatic decision. This step involves the qualitative and quantitative evaluation of comparative organ toxicity, pharmacokinetics, (absorption, distribution, metabolism, and excretion over time), similarity of routes of exposure and the consideration of results from short-term tests. An important qualitative consideration is the judgment as to the relevance of route of exposure. Risk assessment should not use the results of bioassays in which the route of exposure to the sensitive organ is not comparable to potential human exposure or when there is not sufficient metabolism data to compare routes of exposure. Epidemiological data are the most relevant evidence for judging the likelihood that positive results observed in laboratory animals are indicative of potential risk to humans. It must be recognized that, while interpretation of these data is often not simple, they often do provide valuable information.

Genotoxicity. The massive doses used in laboratory carcinogenicity studies increase the probability for the expression of cancer through nongenotoxic mechanisms such as that of recurrent cellular toxicity. If sufficient data exist to demonstrate that a particular chemical does not interact with DNA in vivo or in short-term tests (eg, Ames test, unscheduled DNA synthesis test, mammalian cell mutagenesis, etc), and that the likely mechanism of action is a simple expression of localized toxicity, then the risk assessment should proceed on the basis of the toxicity of the chemical at the site of action rather than the assumption that the chemical is a direct acting systemic carcinogen. In this case the risk assessment should involve models relevant to toxicity, including log-linear and log-probit models, and safety factors.

Nitrilotriacetic acid is one example of a chemical with a relatively large data base that strongly supports the concept of cancer caused by a nongenotoxic mechanism and the existence of a threshold dose. The tumorigenic dose-response is only apparent at high doses and drops off rapidly to a no-observed-effect-level. All the data indicate little or no direct genotoxic activity (Anderson, Alden, and Merski 1982).

An independent multidisciplinary science panel would be especially useful at this point in the decision-making process since the consideration of qualitative factors involves subjective evaluation of data from diverse areas.

Quantitative Considerations

Animal to human extrapolation. Regardless of the method of extrapolating from effects at high doses to effects at low doses, a conversion must be made from animal to human. This must be done using an estimate that incorporates all the appropriate data, rather than using conversion factors that are not based on data. In the rare instance where comparative metabolism or pharmacokinetics data are available, these data must be used to make the animal to human extrapolation.

The general regulatory assumption has been that humans are more sensitive than laboratory animals on a mg/kg basis. This is based upon basic metabolic rates and is quantified by the so-called surface area rule. It is possible that this argument may be justifiable for some direct acting chemicals that require no metabolic activation. However, in the case of chemicals requiring metabolic activation, it can be argued that the correction factor should be just the reverse (Reitz, Gehring, and Park 1978). The peak concentration and total body burden of metabolic products will be higher for the laboratory animals because they metabolize the chemical quickly whereas humans will, in general, form lower concentrations because of the competing effects of elimination and metabolism. In general, it may not be appropriate to use the surface area correction factor in reverse for those chemicals requiring metabolic activation but it *is* implausible to assume that humans are always more sensitive than laboratory animals. This is particularly true when multiple species or strains have been tested and the only tumorigenic response is hepatic tumors in the highly sensitive B6C3F1 mouse. The point is that when interspecies conversion data are available, they must be used rather than relying on a simplistic conversion formula regardless of the data.

Epidemiology. After the animal-to-human extrapolation has been completed, it should be validated against epidemiology data when such data exist. If it can be shown that the model over-predicts or under-predicts the epidemiology experience, then the analysis must be re-done, using the human data as one input.

We have emphasized that quantitative risk assessment, in one form or another, is necessary but that the strict adherence to one specific dose-response model or class of models has failed to adequately characterize potential risk for a number of reasons. These reasons include the inability of present models to incorporate important qualitative data, the inherent problems of extrapolating quantal data far outside the observable range, and the lack of biological foundations for the models. The following approach to risk assessment is an attempt to formalize the considerations made in this section and to use information from the fields of toxicology and statistics to arrive at a logical decision making framework. The framework utilizes dose-response data, but is not greatly dependent on the choice of models. We do not propose this as "the way to do risk assessment"; rather it is a possible way to incorporate statistical models along with the necessary scientific judgment. We are hopeful that the day will soon come when advances in our understanding of carcinogenic mechanisms will allow the incorporation of more mechanistic approaches.

7.2 A Conceptual Model for Risk Assessment and Management

We believe that a number of alternative approaches to risk assessment and management are possible within the framework of the four-step process advocated by AIHC (Figure 1). One possible approach combines the statistical information from the observable dose-response range with the toxicological judgments that are necessary for a logical evaluation of the data. The result is a possible formalization of the many considerations currently used by toxicologists in assessing the potential risks due to chemical exposures. We believe that this approach makes effective use of the available data and scientific judgment. As noted earlier, we provide this concept in the spirit of stimulating discussion on this important subject and providing a direction for future work rather than the presentation of a definitive model that should be used in all cases.

This approach uses the following conceptual model to estimate the safe dose for humans.

$$\text{SAFE DOSE} = D \times \frac{1}{F}(A_1 \times A_2 \times \ldots \times A_n)(M_1 \times M_2 \times \ldots \times M_p)$$

In this model D is either a NOEL, an estimate of a NOEL, or an estimate of a response that is indistinguishable from a NOEL in any standard assay, F is an extrapolation factor based on the NOEL or E-NOEL, and A_i and M_i are factors associated with the risk assessment and risk management functions, respectively. Historically, F has been called a safety factor; however, in order to distinguish between the scientific and regulatory functions, we are calling F an extrapolation factor for it is a function of the scientifically determined best estimate of dose at some desired level of risk (starting from a NOEL or E-NOEL), as distinguished from a societally (regulatory) determined safety factor which is one of the M_i factors in the equation above.

The first step of the procedure is to use the observed dose-response data insofar as it is valid. The dose-response data can be used as a starting point for toxicological interpretation in a number of ways:

- Predict an E-NOEL (see Section 6.1) by a linear or log-linear model, or

- Use one of three or four nonthreshold models that best fits the data (one-hit, multistage, probit, multi-hit), and extrapolate to 1 percent predicted tumor frequency. The models will generally agree quite well down to 1 percent tumor frequency; or,
- Use an experimental NOEL if it exists.

- Another approach, when the data exist, is to estimate D as a NOEL for the associated toxicity rather than tumorigenesis.

- For comparison, each of the above starting points can be modified to incorporate experimental variability in the observed data.

For most applications, the dose D estimated above will be close to the observed dose-response data and represents a limit of the dose-response information. We believe that a logical method for converting this to a safe dose for humans is to use the concept of an extrapolation factor (F) that can be modified up or down by a number of additional factors which represent information from the many types of studies that impact the total hazard potential. Selection of the particular extrapolation factors to use is a critical aspect of this approach. Other people using similar approaches have proposed values between 100 and 1000 but have tended to not separate the various components of the total extrapolation factor (US EPA 1982, Weil 1972, and Kroes 1982). It is important that specific components of the total extrapolation factor be independently considered both from the scientific and societal viewpoints.

The determination of A_i will be subjective and will require an agreement of expert opinion to arrive at quantification. Scientific judgment and the use of extrapolation factors is a better approach, however, than borying biological issues in mathematical sophistication. We note that if one begins with D being the dose associated with a potential risk of 10^{-2} (ie, 1 percent), then $A_i = M_i = 1$ for all i is equivalent to a linear extrapolation down to a dose of $10^{-2}/F$.

Examples of "A_i factors" that may be included in specific cases are:

- Number of positive assays. $A_1 = 1$ if a number of well-designed bioassays are positive. $A_1 > 1$ if only one assay in a highly sensitive species is positive. For instance, the National Cancer Institute bioassay is positive in the mouse, but negative in the rat, $A_1 = 2$ may be reasonable.

- Type of Tumor. $A_2 = 1$ if the compound appears to produce a diversity of tumors. $A_2 > 1$ if the only tumor is a hepatic tumor in B6C3F1 mice, or tumors of the nasal turbinate in an inhalation study of rats.

- Human Epidemiology. If human epidemiology indicates positive results, then either the risk modeling should be done from the human data, if quantitative exposure estimates exist, or $A_3 < 1$ should be used in the above approach. If human epidemiology is negative at exposures greatly in excess of anticipated future exposure conditions, then $A_3 > 1$.

- Time-To-Tumor Data. Exposure to some chemicals causes well-defined increases in tumor frequencies at an early age in animals. Other exposures result in a mixture of increases in frequency of some tumors and decreases in others and are seen only in very old animals. It may be difficult to quantify data of this type but the information is likely to be relevant for evaluating the hazard to humans. An A-factor calculated as a function of the difference or ratio between average latency and median age of death for the strain may be appropriate. For example, A_4 = Average Latency/Median Survival would result in an index that is less than 1.0 for early tumors and greater than 1.0 for old age lesions.

- Pharmacokinetic Data. A_5 can be the ratio of estimated body burdens for laboratory animals compared to humans for the same experimental administered dose (if such data exist). $A_5 > 1$ if pharmacokinetic and metabolic data indicate saturated pathways with resultant disproportionate toxicity at the doses used in bioassays with positive results.

- Approximate slope of the dose-response curve at the low end. In some cases the dose-response curve is relatively steep as it approaches the 1 percent level or NOEL (eg, nitrilotriacetic acid), whereas in other cases is flatter (2-AAF, liver tumors). Although we have argued against extrapolating dose-response curves far beyond the observed data, it may be reasonable in some cases to incorporate a summary measure of slope such as the ratio of the estimated 10 percent response level to the 1 percent response level into the safe dose calculation (ie, ED_{10}/ED_{01}).

- Mechanism. As we understand more about carcinogenesis, the mechanism of action will become increasingly important. At the present, a logical approach would be to set $A_6 = 1$ for chemicals that are directly genotoxic and do not demonstrate any associated toxicity appropriate for predicting real or practical thresholds. On the other hand, if a specific compound has a relatively complete data base showing no in vivo or in vitro indication of interaction with DNA, and tumorigenesis occurs only at levels associated with directly observable toxicity, (eg, cytotoxicity) then A_6 may be increasingly larger than 1 as the data base becomes more complete. A maximum of 10 may be appropriate.

- There are numerous other factors that, on a case-by-case basis, may be used to modify the extrapolation factor F or level of uncertainty (US EPA 1982). These additional factors reflect special knowledge of risk potential associated with a specific situation. It is also imperative that the uncertainty associated with all estimates be communicated to the risk manager in all risk assessments.

A final step in the process is the risk management decision to modify potential human exposures upwards or downwards depending on the statutory findings required (ie, whether the risk is significant or unreasonable) and on the impact of costs, benefits and alternatives, or other factors specified under the law. This should be done last and should be recognized as a subjective societal or political decision (ie, risk management) rather than a scientific one. This can be done by the appropriate assignment of the risk management factors (M_1, M_2, ..., M_p) in the calculation of the estimated safe dose for humans.

It is emphasized that although this estimate of a safe dose has been written in a simplistic equation form, we are recommending an extrapolation factor (historically called safety factor) approach in which the extrapolation factor is modified up or down depending on a number of factors. The A_i and M_i factors should be explicitly considered and judgment made on each independently. It is not possible to state specifically which factors should be included in any given risk assessment or the magnitude of the factors. These decisions must be made on a chemical-by-chemical basis. Nonetheless, we feel this is a workable framework for decision making.

This approach has many of the characteristics of that proposed by Squire (1981b); however, it is more comprehensive because it includes more aspects of the risk assessment process. It is also in keeping with recent regulatory guidelines developed in the Netherlands (Kroes 1982) that make a clear distinction between primarily genotoxic carcinogens and primarily nongenotoxic carcinogens.

AIHC has proposed the use of one or more independent science panels to guide regulatory agencies in the scientific issues involved in risk assessment. In keeping with this concept, a science panel could recommend an appropriate extrapolation factor and could determine which A_i are different from 1, in both the positive and negative direction. The appropriate agency could then carry through the quantitative analysis as well as exposure estimation and the results would be used for appropriate risk management.

8. SUMMARY AND CONCLUSIONS

Our review of risk assessment and management for chemically induced carcinogensis has focused on the use of mathematical models for the quantitative assessment of risk. We have emphasized that the risk analyst should be primarily concerned with scientific issues and the risk manager should deal with the political and social considerations. Each must understand the other's role and viewpoint. Progress is made most rapidly when each considers the other's concerns but does not let these considerations be the driving force in performing their function.

This paper focuses on the risk assessment process for we believe that good risk management decisions will result if the risk assessment is based on good science. Risk assessment is shown to be a complex, multifaceted process that is not easily quantified and is currently based on many qualitative decisions.

It is emphasized that tumor incidence rates chronic exposure studies in animals are only one input to the risk assessment process. At this time statistical models have been developed only for these data; hence, the associated estimates of potential risk provide only one piece of the puzzle. The statistical models are useful summarizing dose-response relationships and comparing dose-response relationships among chemicals within the observable dose-response range.

Extrapolations of tumorigenic responses to very low doses by means of mathematical models are of limited value because the models can have no validated biological basis "since these are not known for any carcinogen" (Squire 1981b). Certainly, any extrapolations should be made with great care and only in conjunction with a variety of supporting data. To do otherwise amounts to nothing more than a blind curve fitting exercise with little predictive value.

There is also a need to develop risk assessment models that allow for differences due to species, tumor type, spontaneous incidence, sex, strain, genotoxicity, pharmacokinetics, etc. Since these important considerations as well as level of human exposure, epidemiology, and data on other toxicological end points are not presently considered by the statistical models, decisions concerning acceptable exposures should be based on a variety of inputs that include the results of statistical modeling. It is unlikely that the regulatory decision process will be even largely quantified by a single model, or group of models, in the near future.

We are not saying that the statistical approach is of no value. On the contrary, science moves forward most rapidly when the basic mechanisms can be understood, quantified, and modeled. We feel that much progress will be made when the statistical models are expanded to encompass and quantify more of the risk assessment process. Much research work must be done to accomplish this goal.

ACKNOWLEDGEMENTS

The authors are pleased to thank P. F. Deisler, Jr., R. C. Barnard, and the members of the AIHC Subcommittee on Quantitative Risk Assessment, in particular, D. H. Hughes, J. T. Barr, and R. D. Bruce, for their helpful comments and suggestions on the presentation of this paper.

R. D. Snee
C. H. Park
8/2/82

9. REFERENCES

American Industrial Health Council (1981). Chronic health hazards: Carcinogenesis, mutagenesis, teratogenesis. A framework for sound science in federal decision making. A statement by the American Industrial Health Council, 1075 Central Park Avenue, Scarsdale, NY, Draft for external review, October 30, 1981.

Anderson, M. W., Hoel, D. G. and Kaplan, N. L. (1980). A general scheme for the incorporation of pharmacokinetics in low-dose risk estimation for chemical carcinogenesis: Example - vinyl chloride. Toxicology and Applied Pharmacology, 55, 154-161.

Anderson, R. L., Alden, C. L. and Merski, J. A. (1982). The effects of nitrilotriacetic acid on cation disposition and urinary tract toxicity. Food and Cosmetics Toxicology, 20, 105-122.

Berenblum, I. (1929). Tumour-formation following freezing with carbon dioxide snow. British Journal of Experimental Pathology, 10, 179ff.

Box, G. E. P. (1979). Robustness in the strategy of scientific model building. In Robustness in Statistics, Launer, R. L., and G. N. Wilkinson, Editors, Academic Press, NY, 201-236.

Brown, C. (1978). Statistical aspects of extrapolation of dichotomous dose response data. Journal of the National Cancer Institute, 60, 101-108.

Bruce, R. D. (1980). Low-dose extrapolation and risk assessment. Chemical Times and Trends, October 1980, 20-23.

Carlborg, F. W. (1981a). Dose-response functions in carcinogenesis and the Weibull model. Food and Cosmetics Toxicology, 19, 255-263.

Carlborg, F. W. (1981b). 2-Acetylaminofluorene and the Weibull model. Food and Cosmetics Toxicology, 19, 367-371.

Carter, L. J. (1979). How to access cancer risks. Science, 204, 811-816.

Cornfield, J. (1977). Carcinogenic risk assessment. Science, 198, 693-699.

Crump, K. S. (1981). An improved procedure for low-dose carcinogenic risk assessment from animal data. Journal of Environmental Pathology and Toxicology.

Crump, K. S. (1982). Designs for discriminating between binary dose-response models with applications to animal carcinogenicity experiments. Communications In Statistics, Theory and Methods, 11, 375-393.

Doll, R. (1971). Age distribution of cancer. J. Royal Statistical Society, Series A, 134, 133-166.

Food Safety Council (1980). Quantitative risk assessment. In Proposed System for Food Safety Assessment, 137-160. Food Safety Council, Washington, DC.

Gaylor, D. W. and Kodell, R. L. (1980). Linear interpolation algorithm for low-dose risk assessment of toxic substances. Journal of Environmental Pathology and Toxicology, 4, 305-312.

Gehring, P. J. and Blau, G. E. (1977). Mechanisms of carcinogenesis: Dose response. Journal of Environmental Pathology and Toxicology, 1, 163-179.

Gehring, P. J., Watanabe, P. G. and Park, C. N. (1979). Risk of angiosarcoma in workers exposed to vinyl chloride as predicted from studies in rats. Toxicology and Applied Pharmacology, 49, 15-21.

Gibson, J. E. (1982). Risk assessment using a combination of testing and research results. In Proceedings of the Third Annual Chemical Industries Institute of Toxicology Conference, 'Formaldehyde Toxicity', Ed. J. E. Gibson, Hemisphere, NY, In press.

Hoel, D. G. (1981). Carcinogenic risk: Comment on "Regulation of Carcinogens" by E. Crouch and R. Wilson. *Risk Analysis*, *1*, 63-64.

Krewski, D. (1981). Simulation of low-dose extrapolation procedures. Presented at the Workshop on Biological and Statistical Implications of the ED_{01} Study and Related Data Bases, sponsored by the Society for Toxicology and National Center for Toxicological Research, Deer Creek State Park, Mt. Sterling, OH, September 13-16, 1981.

Krewski, D. and Brown, C. (1981). Carcinogenic risk assessment: A guide to the literature. *Biometrics*, *37*, 353-366.

Krewski, D. and Van Ryzin, J. (1981). Dose response models for quantal response toxicity data. In *Current Topics in Probability and Statistics*, M. Csorgo, D. Dawson, J. N. K. Rao and E. Saleh (eds). New York: North-Holland. To appear.

Kroes, R. (1982). International Life Sciences Institute Workshop on Carcinogenic Mechanisms, Amelia Island, Florida, March 16-19, 1982.

Laroye, G. J. (1974). How efficient is immunological surveillance against cancer and why does it fail. *Lancet*, *1*, 1097ff.

Munro, I. and Krewski, D. (1981). Risk assessment and regulatory decision making. *Food and Cosmetics Toxicology*, *19*, 549-560.

National Academy of Sciences (1980). *Regulating Pesticides*, Report of the Committee on Prototype Explicit Analyses for Pesticides, Environmental Studies Board, Commission on Natural Resources National Research Council. Chapter 1.

Ramsey, J. C., Park, C. N., Ott, M. G. and Gehring, P. J. (1979). Carcinogenic risk assessment: Ethylene dibromide. *Toxicology and Applied Pharmacology*, *47*, 411-414.

Reitz, R. H., Gehring, P. J. and Park, C. N. (1978). Carcinogenic risk estimation for chloroform: An alternative to EPA's procedures. *Food and Cosmetics Toxicology*, *16*, 511-514.

Salsburg, D. (1981). Re-examination of the ED_{01} Study-Adjusting for time on study. *Fundamental and Applied Toxicology*, *1*, 81-87.

Sielken, R. L., Jr. (1981). Re-examination of the ED_{01} Study-Risk assessment using time. *Fundamental and Applied Toxicology*, *1*, 88-123.

Squire, R. A. (1981a). Limitations of histopathology analysis. Presented at the Workshop on Biological and Statistical Implications of the ED_{01} Study and Related Data Bases, sponsored by the Society for Toxicology and National Center for Toxicological Research, Deer Creek State Park, Mt. Sterling, Ohio, September 13-16, 1981.

Squire, R. A. (1981b). Ranking animal carcinogens: A proposed regulatory approach. *Science*, *214*, 877-880.

St. John, D. S., Bailey, S. P., Fellner, W. H., Minor, J. M., and Snee, R. D. (1982). Time series analysis of stratospheric ozone. *Communications In Statistics*. In press.

Stott, W. T., Reitz, R. H., Schumann, A. M. and Watanabe, P. G. (1981). Genetic and nongenetic events in neoplasia. *Food and Cosmetics Toxicology*, *19*, 567-576.

Todhunter, J. A. (1982). Review of data available to the Administrator concerning formaldehyde and di (2-ethylhexyl) phthalate (DEHP). U.S. Environmental Protection Agency Memorandum, Office of Pesticides and Toxic Substances, Washington, DC, February 10, 1982.

U. S. Environmental Protection Agency (1982). Report on Workshop on Estimating Ambient Water Quality Criteria for Epigenetic Carcinogens. Sponsored by EPA Environmental Criteria Assessments Office, 26 West St. Clair Street, Cincinnati, Ohio, February 17, 1982.

Van Ryzin, J. (1981). Review of statistics - The need for realistic statistical models for risk assessment. Fundamental and Applied Toxicology, 1, 124-126.

Wahrendorf, J. (1979). The problem of estimating safe dose levels in chemical carcinogenesis. J. Cancer Research and Clinical Oncology, 95, 101-107.

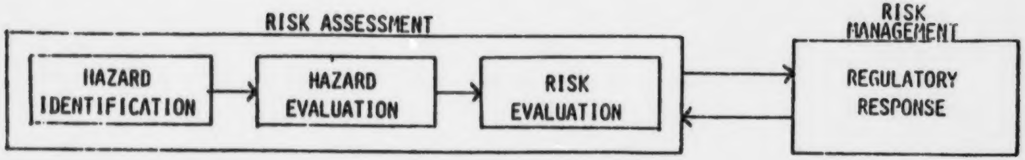
Weil, C. S. (1972). Statistics versus safety factors and scientific judgment in the evaluation of safety for man. Toxicology and Applied Pharmacology, 21, 454-463.

Weisburger, J. H. and Williams, G. M. (1980). Chemical carcinogens. Toxicology, The Basic Science of Poisons, 2nd Edition, Casarett and Doull, Editors, Macmillan, NY, 84-138.

Weisburger, J. H. and Williams, G. M. (1981). Carcinogen testing: Current problems and new approaches. Science, 214, 401-407.

Figure 1

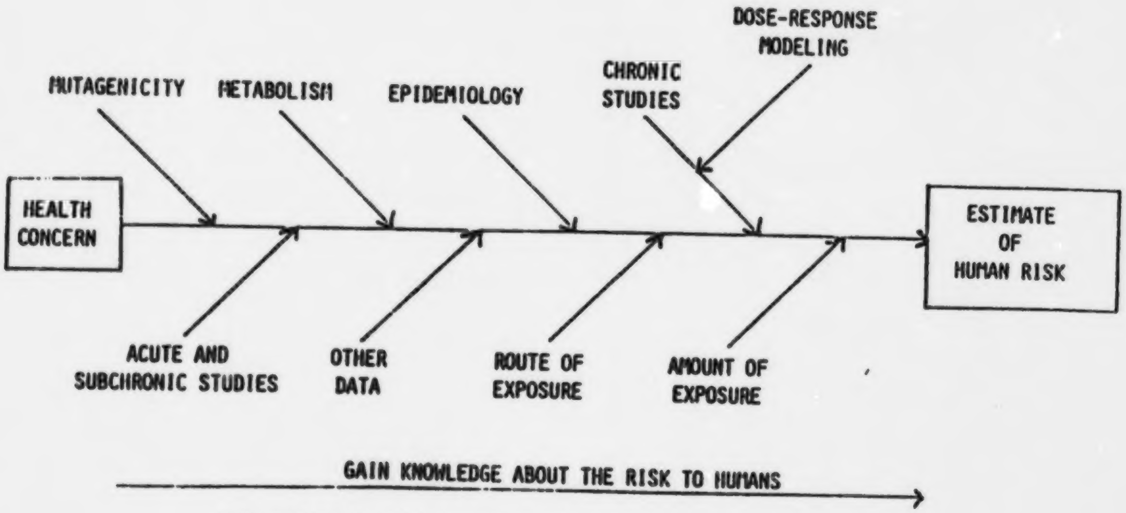
RISK ASSESSMENT AND MANAGEMENT


RISK ASSESSMENT
HAZARD IDENTIFICATION
HAZARD EVALUATION
RISK EVALUATION
RISK MANAGEMENT
REGULATORY RESPONSE

The four major steps in the process of risk assessment and management. AIHC uses the term Regulatory Response for the risk management step.

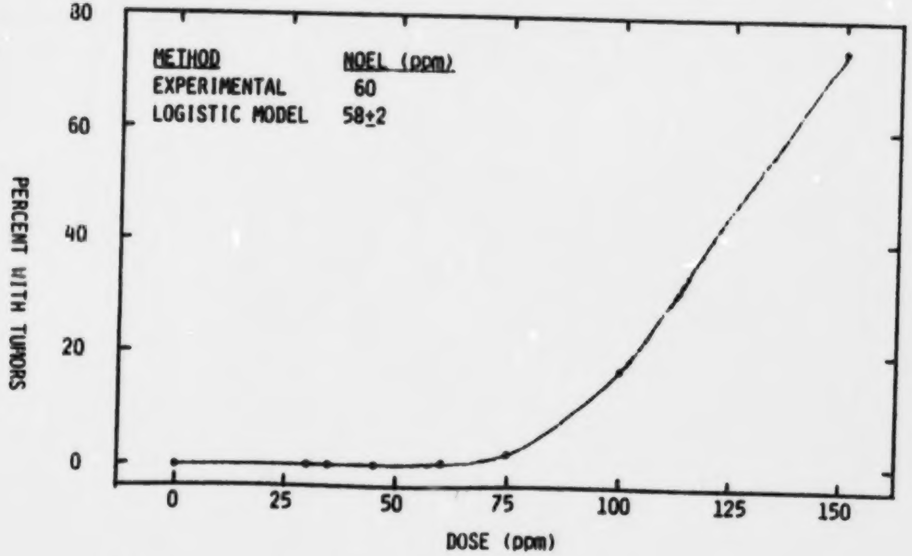
Figure 2

DATA USED IN THE RISK ASSESSMENT PROCESS


DOSE-RESPONSE MODELING
MUTAGENICITY
METABOLISM
EPIDEMIOLOGY
CHRONIC STUDIES
HEALTH CONCERN
ESTIMATE OF HUMAN RISK
ACUTE AND SUBCHRONIC STUDIES
OTHER DATA
ROUTE OF EXPOSURE
AMOUNT OF EXPOSURE
GAIN KNOWLEDGE ABOUT THE RISK TO HUMANS

Data used in the risk assessment process. Dose-response models are used only in the analysis of the tumor incidence data collected in the chronic studies in animals.

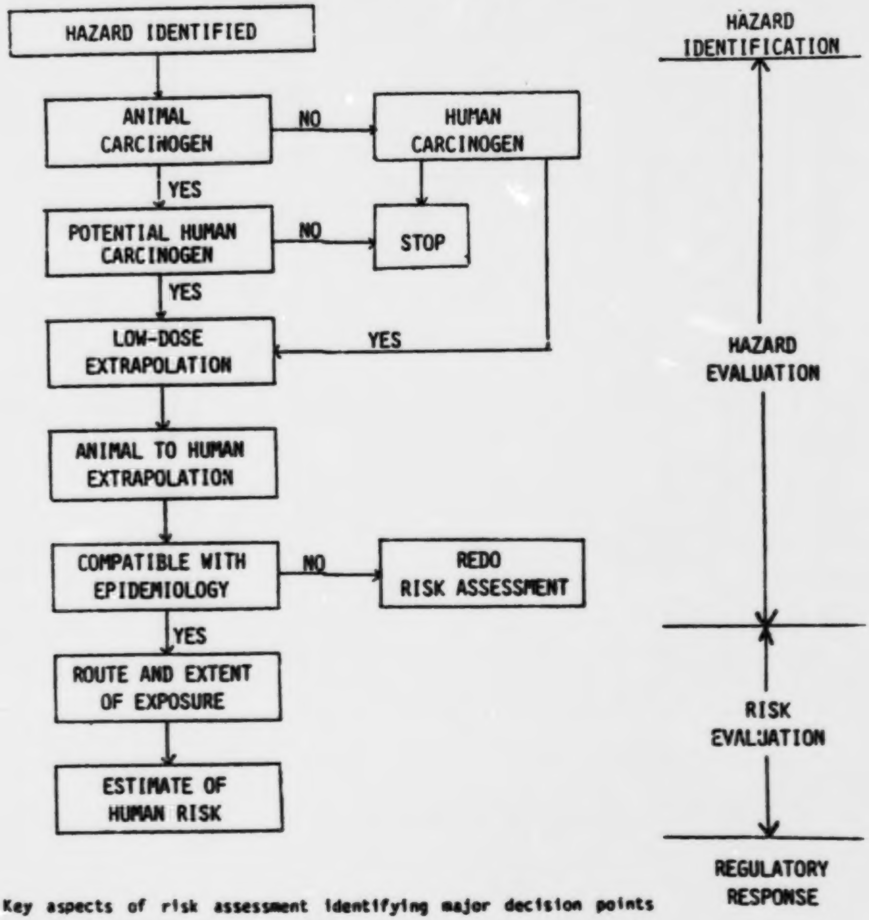
Figure 3. EFFECT OF 2-AAF ON BLADDER TUMORS IN MICE



Dose-response of 2-AAF for bladder tumors in mice (data from Bruce 1980). The no-observed-effect-level is 60 ppm. The estimated-no-observed-effect-level based on the logistic model is 56 ppm with 95 percent confidence limits of ± 2 ppm.

Figure 4

KEY ASPECTS OF RISK ASSESSMENT


HAZARD IDENTIFIED
ANIMAL CARCINOGEN
NO
HUMAN CARCINOGEN
YES
POTENTIAL HUMAN CARCINOGEN
NO
STOP
YES
LOW-DOSE EXTRAPOLATION
YES
ANIMAL TO HUMAN EXTRAPOLATION
COMPATIBLE WITH EPIDEMIOLOGY
NO
REDO RISK ASSESSMENT
YES
ROUTE AND EXTENT OF EXPOSURE
ESTIMATE OF HUMAN RISK
HAZARD IDENTIFICATION
HAZARD EVALUATION
RISK EVALUATION
REGULATORY RESPONSE

Key aspects of risk assessment identifying major decision points and showing their relation to AIHC's four step risk assessment and management process.

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1982 October 15

Dr. J.F. Mustard, M.D.
Office of the Chairman
Advisory Council of Occupational
Health and Occupational Safety
400 University Avenue
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

It was suggested in your letter of 1982 June 30 that Du Pont Canada Inc. might provide comment on Council's Discussion Paper "The Control of Workplace Carcinogens". We are most pleased to do so.

For a number of years we have had Corporate guidelines in place to help ensure that prompt assessment is made of any carcinogenic risk from exposure to hazardous chemicals involved in the manufacture, use, distribution or disposal of our products, and that programs to minimize such risk are developed when necessary. Based on our years of experience in dealing with such evaluation, assessment and control of carcinogenic risk, we feel that we are in a position to make a valid contribution with respect to the regulatory options relating to this important area. As you will recall, our views on these matters were presented to Council in 1981 September. In addition to our comments on the Discussion Paper, I have included, as part of our submission, a copy of those presentations for your convenience.

We would be pleased to enter into further discussion with Council on any of the points raised.

Yours truly,

DU PONT CANADA INC.

D.H. Dawes

D.H. Dawes
Manager, Environmental Science

Dupont Canada Inc.

October, 1982

REPORT TEXT	COMMENT
1. In the case of new chemicals, potential carcinogenicity can be established and appropriate regulations and controls decided upon before the substances become an inextricable part of an operating system or process. (Page 2, par. 1, line 4.)	The indicated statement that potential carcinogenicity be established before a chemical substance becomes an inextricable part of an operating system or process, is a position that could prove so costly that innovation in Ontario industry would be stifled. We support the position that a review and assessment of all new chemicals for potential toxic properties should routinely be made. In most cases, such review will not involve full testing to establish whether or not such substances are carcinogenic. To do so would be exceedingly costly, with 2-year animal studies costing in excess of 1/2 million dollars, and with there being a great lag time between the start of a test and completion and evaluation of the results of such tests. It has been our experience that not many chemicals require such exhaustive test programs at the outset of their commercial life.
2. The lesson which emerges from such a debate is that in establishing controls for new substances, estimates of risk will generally have to be made without the assistance of epidemiologic data. There is, therefore, an urgent need to ensure that there is a record of the health effects where workers have been inadvertently exposed to carcinogens. (Page 7, par. 1, line 1.)	The two sentences indicated opposite are inconsistent in that the first deals with the need for establishing controls for new substances while the second sentence goes on to say that there is an urgent need to keep a record of health effects, presumably for existing chemical substances. This portion of the report should be clarified.

REPORT TEXT	COMMENT
3. It must, however, be recognized that any independent action on the part of the Government of Ontario in controlling carcinogens and suspect carcinogens, would be of limited effect and could have potentially serious and disruptive economic implications if proposals for regulation were not coordinated with existing and anticipated regulatory schemes at the federal and other provincial levels. It is important, therefore, that representations be made to the federal government, calling for assistance in the financing of individual provincial initiatives and for the establishment and coordination of a nationwide program. (Page 8, par. 2, line 7.)	We support the recommendation of the Advisory Council that Ontario seek to obtain a uniform policy on carcinogens across Canada. To have differing standards and differing test requirements, one province to another, would severely impede interprovincial commerce. On the subject of financing of individual provincial initiatives, we have no comment.
4. In developing this scheme, Council has considered the approach adopted in other jurisdictions, including the European Economic Community and the policy under consideration in the United States. There appears to be a general acceptance of the philosophy that all new chemicals should be screened and that if any are found to be carcinogens or potential carcinogens, their application in industry should be regulated. (Page 9, par. 3, line 1.)	We support the position of the Advisory Council in seeking to harmonize its policies relative to the identification and regulation of carcinogens with those that are in place in other jurisdictions with which Canada has significant trade relations. With regard to the philosophy that all new chemicals should be screened, we agree that screening, if it is interpreted to mean the review of the potential of a chemical to pose a risk under its conditions of use or manufacture, should be done. However, we do not agree that short term screening tests can positively identify carcinogens. Rather than limiting the Ministry's screening of new chemicals to an evaluation of the carcinogenic potential of such chemical, the Ministry should screen for all adverse health effects. Rather than simply requiring that the chemicals be subjected to a specified battery of tests, the manufacturer should submit a risk assessment which would provide information on the test data that are available, the structure-activity relationship between the new chemical and existing chemicals, if appropriate, the physical properties of the chemical, and the potential for exposure. With sufficient input from the manufacturer or importer of such new chemical, the Ministry should be able to determine whether or not a chemical can safely be manufactured or used for its intended purpose.

REPORT TEXT	COMMENT
5. Regulations for the control of carcinogens and suspect carcinogens, to be used in the workplace in Ontario, could be established by the Minister, after appropriate public discussion. In reaching his final decision, the Minister might wish to consult solely with ministry staff. Alternatively, he might supplement the advice provided by his ministry with opinions offered by an advisory committee or committees struck by the Minister, for the purpose of advising on this and other aspects of the regulatory program. Any such committee(s) should be established by the Minister after full consultation with all the groups involved in the area. Its membership should be broadly representative of the various groups and its advice should be made public. The committee might be advisory to the Minister himself, or to the ministry. (Page 10, par. 1, line 1.)	Du Pont Canada Inc. supports the concept of an advisory committee to counsel the Minister after appropriate regulatory action has been established. However, we think that care must be taken in establishing such an advisory committee in that the make-up of the committee should be balanced and not represent one segment of the community, and secondly, that the committee's focus be appropriate. That is to say, that where a committee is to review scientific data or establish a test program, its membership should consist of individuals with expertise in the relevant fields of science. Where the committee is to be used to advise the Minister on regulatory policy, it should include individuals with practical knowledge of the regulated industry, as well as academics and public representation.
6. The responsibilities of the advisory committee might include the following: 1) To advise the Minister on testing procedures and to approve guidelines for interpreting the results of short term and animal tests. 2) To offer advice to the Minister, in the circumstances described below, on the need for testing, or further testing, of certain chemical substances. 3) To recommend to the Minister, in the circumstances described below, the appropriate categories for chemical substances. 4) To make recommendations to the Minister with regard to the suitability of substitutes for known carcinogens. 5) To advise the Minister on the appropriate regulatory controls for carcinogens and suspect carcinogens. (Page 10, par. 2, line 1.)	With the above comments in mind, we would suggest that the types of advice called for in items 1, 2 and 3, would properly be the subject of a peer review type committee which would be composed primarily of scientists. With regard to item 4, the committee make-up should include medical personnel, scientists, industrial hygienists, and policy makers. With regard to item 5, the committee could appropriately comprise medical personnel, industrial hygienists, engineers, members of the public and academia, and members with industrial operating experience. Thus, as can be seen by the above, a single advisory committee would not appear to be appropriate to do all of the tasks that have been set, but rather committees tailored to the Minister's needs for counsel, should be established. Consideration might also be given to the establishment of a coordinating committee through which the results of the efforts of the other committees could flow to the Ministry.

REPORT TEXT	COMMENT
7. In deciding upon the appropriate regulatory controls for workplace carcinogens and suspect carcinogens, account should be taken of the risk which each of these agents poses to humans. This assessment should be based in part on the tumor-inducing potency of the compound in animals. Present knowledge, however, does not enable this to be done with any precision and the decisions would have to take note of this uncertainty. In addition, economic and social considerations would have to be weighed in arriving at the appropriate regulatory controls. (Page 11, par. 1, line 1.)	This paragraph succinctly sets forth the proper goal of regulation of carcinogens at the present time. It recognizes that all factors that enter into the decision of whether or not a substance poses a carcinogenic risk must be considered, but that even when such factors are considered in reaching a decision, that decision is less than precise. For this reason, both economic and social considerations should be weighed when determining whether or not regulatory controls should be put into place and what such regulatory controls should be.
8. Identification and Classification Three categories might be employed: Category I - Substances confirmed as human carcinogens. Category II - Substances about which there is some uncertainty as to their carcinogenicity. Category III - Substances which are considered to be non-carcinogenic. (Page 12, par. 1, line 1.)	The Ministry should recognize that suggestive but not conclusive data often exist so that Category II is likely to contain many more substances than either I or III. For this reason, as we will discuss in greater depth, the Ministry must assess the potential risk of each substance in Category II and prioritize further testing accordingly.
9. Slightly less stringent requirements could apply in the case of substances to be marketed in quantities of less than one tonne per annum, as discussed below. (Page 12, par. 3, line 6.)	We agree that less stringent requirements should apply in the case of substances that are marketed in low volumes and a one tonne per annum limit is one that has been used in other jurisdictions. We also agree that some assessment of the potential harm of the substance should be made whether or not it is marketed in one tonne a year amounts or higher. Thus, the combination of a reasonable assessment, coupled with exemption from the full assessment requirements, is appropriate.

REPORT TEXT	COMMENT
10. In developing the information needed to meet the reporting requirements, all new chemicals should be assessed for their chemical structure and relationship to known carcinogens. (Substances should be assessed as used because of the likely presence of impurities.) Where, after the initial assessment, it was determined that the chemical structure of the substance was similar to that of a known carcinogen, where it was known to be subject to tissue accumulation, or where earlier studies suggested that long term exposure might lead to the development of cancer, the substance should go directly into long term animal testing, regardless of the quantities to be used. Where the results of these tests were positive, the substance should be placed in Category I. Where they proved non-positive, the results could be referred to the advisory committee which would advise the Minister on whether the substance should be placed in Category II or III. (Page 13, par. 2, line 1.)	Structure alone should never be the sole criteria for deciding to require a full-scale lifetime bio-assay for carcinogenicity. Structure-activity relationships are important considerations, but all other toxicity and potential exposure information is essential to developing a reasonable testing program. As more thoroughly discussed in response to Issue #4, we believe that chemicals should be subjected to appropriate tests to enable manufacturers and regulators to properly assess the hazards of the chemicals in use in Ontario and to ensure that proper precautions are used to minimize risks from exposure. We also believe that the reality of the limited facilities available for animal testing must be considered in mandating long term testing. Therefore, it may not be prudent to test a suspect material whose use is very low or whose exposure potential is very low when testing of a substance with a greater potential for exposure would be delayed.
11. It would therefore, have to be made clear that if members of the committee had any doubts whatsoever about the safety of a substance, the appropriate recommendation would be to place it in Category II. (Page 14, par. 1, line 5.)	The thread running throughout the report leads us to conclude that the bulk of substances will be placed in Category II, that such category would be essentially meaningless, with few substances being designated as proven carcinogens and few substances designated as completely safe and non-carcinogenic. Therefore, the Ministry should be prepared to deal with the substances in Category II on a case-by-case basis determined by the relative potential risk from use of each substance.
12. Where the initial assessment did not indicate an immediate need for animal tests, (and the developers themselves did not decide to have the substance subjected to animal testing at that stage) all new chemicals to be marketed in quantities of one tonne per annum or more, should be subjected to short term tests.	All new chemicals should not be subjected to short term tests. Any such decision should be based on consideration of many factors such as chemical structure, physical properties of the chemical, intended use, the potential for exposure to the chemical and the known relationship between the new chemical and chemicals that are already on the market. These, in many instances, can provide sufficient evidence upon which a risk assessment can be made.

REPORT TEXT	COMMENT
	If this analysis indicates a need for testing, then an appropriate protocol can be developed, perhaps beginning with a battery of short term tests.
13. If the results of the short term tests were positive, or conflicting, the substance should automatically undergo long term animal tests. (Page 14, par. 3, line 1.)	Irrespective of the results of short term tests, it should not be concluded that long term testing automatically be undertaken. Some short term tests results may be more significant than others and conflicting results should not automatically result in a long term bio-assay; for example, even though a compound causes mutations in one of the Ames Test strains, an animal bio-assay would not be the logical step if it also is negative in all other assays including an in vivo model. A more flexible approach should be adopted. For example, if a chemical can be manufactured and used with a low probability of exposure, both the manufacturer and the government may prefer to implement a control scheme or to require use of protective equipment to ensure that no exposure occurs, rather than undertaking the costs of additional testing.
14. If the results of the short term tests were non-positive, the manufacturer or user should have the option of either putting the substance into long term animal tests or having it referred to the advisory committee. If the manufacturer chose to go directly to animal tests, the substance would be classified as follows: If the results proved positive, the substance would be placed in Category I. If the results were non-positive, it would be placed in Category III. (Page 15, par. 1, line 1.)	Short term tests do have relevance and should not be ignored as apparently is contemplated by this paragraph. Also, there are too many chemicals in commerce in Ontario to test and there is a definite need to prioritize which substances would be tested. If the short term tests are negative, and if other information is not suggestive of a carcinogenic risk, rather than requiring further testing we believe the material should be placed in Category III.
15. Category II - Substances about which there is some uncertainty as to their carcinogenicity would be controlled as suspect carcinogens. (Page 16, par. 2, line 7.)	All of the many substances which may be in Category II should not be controlled as suspect carcinogens. Each one should be subjected to a thorough evaluation including all toxicology data and human experience. If the data suggest that a significant risk is likely at the expected levels of exposure, then appropriate controls to reduce that risk should be imposed. The Ministry will find in many cases, that the data are equivocal and regulation may not be appropriate.

REPORT TEXT	COMMENT
16. The establishment of testing requirements and regulatory controls must be accompanied by an effective means of enforcement. One method of ensuring compliance is through a permit or licensing system, whereby no carcinogen or suspect carcinogen can be used unless duly authorized by the competent authority. The licensing system for radioactive isotopes might serve as a model. (Page 17, par. 1, line 1.)	One need not undertake a positive licensing approach as suggested in this paragraph, to assure protection of the workforce from chemicals posing specific hazards. A system such as that employed in the United States and other countries in which an acceptable exposure limit would be achieved by engineering controls or such other controls as the Minister would deem appropriate, could be most effectively employed, thereby avoiding the need to review each specific adverse health effect and grant a license relating to such effect for a given chemical. For example, some chemicals that pose a carcinogenic hazard might also pose a teratogenic hazard. By controlling the exposure to the lowest level at which an effect is seen, one would protect the workforce for all adverse effects and compliance could be ensured through an inspection system rather than a licensing system which could prove to be unduly cumbersome.
17. The actual day to day monitoring of the use of new substances can only occur in the workplace itself. Employers should be required to disclose to the joint health and safety committees, or to the workforce where no committees are established, information about new chemicals and possible hazards. All containers in use should be meaningfully labelled with highly visible, colour coded indications of carcinogenic hazard. (Page 17, par. 2, line 1.)	We do not oppose making information on the hazards of substances to which the workforce is exposed available to workers or to their representatives. However, we do believe it is appropriate that a mechanism for protecting trade secrecy of such information be supported by the Advisory Council. The methodology of hazard information transmittal will need to be reviewed further as labels are only part of such a system.
18. If management failed to do so, members of the committee, or of the workforce, should have the right to ask the government to take appropriate action, which might entail the imposing of a suitable financial penalty. Some have even considered the idea that offending parties should lose their protection from civil liability under the Workmen's Compensation Act, if problems subsequently arose. (Page 17, par. 3, line 4.)	We believe that the sentence that poses elimination of the existing Workmen's Compensation scheme should be eliminated as being an over-reaction to what may be an inadvertent or innocent failure on the part of the employer. In addition, this ascribes to occupational health (carcinogenicity), a different standard, a selective application of harsh penalties to workplace hazards and there is no reasonable basis for such.

REPORT TEXT	COMMENT
19. Substances which were not new - i.e. those on the Environmental Protection Agency (EPA) list or those currently in use in Ontario - should, where appropriate, be subject to the above testing procedures unless sufficient data were already available for them to be accurately categorized. (Page 18, par. 2, line 1.)	We have a number of comments on this item. The combination of these two groups of substances will exceed 60 000 substances and without some restriction, the review and prioritization of all of these existing chemicals would be exceedingly burdensome to the Ministry. With regard to specific provisions of this item, there should be some definition of the meaning of the phrase "where appropriate" when determining which substances are to be subject to the testing procedures that are outlined in the report. In addition, it should be recognized that not only test results provide additional data, but as stated earlier, the potential for exposure, the physical properties of the substance, and their relationship to existing chemicals, the properties of which are known, should also be taken into account in deciding whether or not to test.
20. Priorities should be set for testing of such substances. (Page 18, par. 2, line 9.)	We agree that it will be necessary to establish priorities for testing of existing chemicals. However, the Advisory Council should provide some guidance as to how these priorities will be established.
21. Expenses of such testing should be borne by the manufacturer of a substance currently in use in Ontario. (Page 18, par. 2, line 10.)	We do not agree that the expenses of testing should be borne by the manufacturer of a substance that is currently in use in Ontario. Where the substance is manufactured outside of Ontario, the importer should be the individual to whom Ontario looks for support of testing. However, where the foreign manufacturer in that instance has conducted testing, these test results, wherever possible, should be accepted by the Minister in conducting the evaluation of the carcinogenicity of the substance. Further, where more than one manufacturer is present in Ontario, the expenses of conducting the tests should be reasonably related to the contribution of the manufacturer or user to the exposure to the substance. That is, if one manufacturer uses a substance captively and in an enclosed system, while a second manufacturer sells the substance for

REPORT TEXT	COMMENT
	numerous uses in the merchant market, the first manufacturer should not share equally in the testing costs since that manufacturer contributes very little to potential exposure.
22. The Ministry should make a systematic attempt to have the substances on the EPA list and those currently in use in Ontario, properly categorized within a period of five years. (Page 18, par. 3, line 1.)	The five year period established for categorizing all of the existing chemicals in Ontario is an unduly short period of time. What must be done by the Ministry is to review first those chemicals with the greatest potential for harm and proceed on down the list in a regular fashion until all chemicals have been evaluated. To establish a limit of five years with the resources available in the Province of Ontario for testing and evaluation of chemical substances would represent an impossible target.
23. It would probably be advisable for the Ministry to do this in collaboration with other jurisdictions or organizations such as the International Labour Organization. (Page 18, par. 3, line 3.)	We believe this collaboration should be done with other regulators, and other government agencies within and outside Canada. It should be remembered that some of the information that the government will receive has confidentiality restraints.
24. Where a chemical which was not considered new, was to be used in a newly constructed plant, either built from ground up or converted for different purposes, it should be automatically subject to the same testing and classification procedures as employed for new chemicals. (Page 19, par. 1, line 1.)	The proposal in question would be anti-competitive and contrary to the best interests of the province since it would discourage existing manufacturers from expanding within Ontario and could discourage new manufacturers from coming into the Province of Ontario if such manufacturer would be faced with a known bill of more than 1/2 million dollars for each chemical that would be used in the plant unless that chemical had, in fact, been reviewed by the Ministry and its regulatory fate decided. Secondly, the Ministry should, as indicated above, evaluate chemicals based on their potential for harm rather than on whether or not they are being used in new plant operations. Where such chemicals are high on the Ministry priority list, the additional exposure that could arise from manufacture or use in a new facility could trigger an earlier decision to require testing or

REPORT TEXT	COMMENT
	other regulation, but this should be only one factor and should not be the controlling factor in a decision to test or classify the material.
25. Issue #1 - National and International Coordination and Cooperation in the Control of Carcinogens	
1) Should representation be made, through the appropriate channels, to the federal government calling for assistance in the financing of individual provincial initiatives and for the establishment and coordination of a nationwide carcinogen program, through agencies such as the federal Department of Labour, the Department of National Health and Welfare and the Canadian Centre for Occupational Health and Safety?	We suggest that a nationwide carcinogen program be established through a federal-provincial task force made up of all interested parties. Health and Welfare and Labour Canada might assume the lead role on such a task force. This program might be patterned in principle after the present federal-provincial task force program on workplace hazard communication.
2) As part of a national program, should the federal government or national agency be encouraged to give the highest priority to the objective of assembling and co-ordinating the available data from this and other jurisdictions, with regard to the carcinogenicity and potential carcinogenicity of chemical substances?	Assembling and coordinating data on carcinogenicity would undoubtedly be one of several key priority areas of interest within a national program. However, specific priorities should be established by the federal-provincial task force as a first order of business.
3) In establishing priorities for the testing of chemicals and in deciding upon appropriate regulatory controls for carcinogens and suspect carcinogens, should the Ontario Ministry of Labour work in close collaboration with international organizations such as the International Labour Organization? Should due regard be paid to international agreements such as the ILO "Convention concerning prevention and control of Occupational Hazards caused by Carcinogenic Substances and Agents"?	The Ontario MOL, through the federal-provincial task force, should be aware of, and if appropriate, be prepared to work with any national or international authority recognized to have expertise in the field. In establishing priorities for the testing of chemicals and in deciding upon appropriate regulatory controls, Canada should be well aware of the corresponding positions, either in place or being considered by its major trading partners.

REPORT TEXT	COMMENT
26. Issue #2 - Advisory Committee(s) Should an advisory committee(s) be established with the responsibility for advising the Minister (or the Ministry) on all aspects of the regulatory program for carcinogens? In particular, should the advisory committee make recommendations with regard to the appropriate categories and regulatory controls for chemical substances? Should the criteria applied by the committee be subject to periodic review by the Ministry?	The comments will be similar to those that were provided above, and that is that we would recommend that more than one committee be established to advise the Ministry since it has been demonstrated in other jurisdictions that such committees can be of value to a regulator. These committees need to be selected to accomplish a specific purpose. For example, scientists should be on a committee that would perform peer review functions to determine whether adequate scientific evidence is present in the documentation. A policy-making committee could include scientists, economists, industrialists and other representation. These committees should be strictly advisory in nature, with the Minister making the final determination.
27. Issue #3 - Reporting Requirements for New Chemicals 1) Should the Minister establish reporting requirements for full disclosure of the possible carcinogenicity of any new chemical to be introduced into the workplace in Ontario?	It is our view that the existing legislation in Ontario, regarding notification of new substances in Ontario, should be allowed to work before additional reporting requirements are imposed upon new chemicals. It is our view that the Minister should be advised of all toxicity information that is relevant to the manufacture or use of the chemical in Ontario and that information on carcinogenicity or potential carcinogenicity would be only one factor in this reporting scheme. Thus, the bottom line is that we believe that there is a mechanism in place which will accomplish the desires of the Advisory Council.
2) Should limited reporting requirements apply to new chemicals to be marketed in quantities of less than one tonne per annum unless, after an initial assessment, they were considered suspect?	We agree that less stringent requirements should apply in the case of substances that are marketed in low volumes and a one tonne per annum limit is one that has been used in other jurisdictions. We also agree that some assessment of the potential harm of the substance should be made whether or not it is marketed in one tonne a year amounts or higher. Thus, the combination of a reasonable assessment, coupled with exemption from the full assessment requirements is appropriate.

REPORT TEXT	COMMENT
28. Issue #4 - Testing Requirements for New Chemicals 1) Should the Minister establish regulations calling for the examination of all new chemicals on the basis of their chemical structure and relationship to known carcinogens?	We believe that it is advisable for the Minister to establish guidelines that would apply to an examination of all new chemicals. These guidelines should not be limited strictly to an assessment of the potential toxicity based on structure and relationship to known carcinogens, but also include any known toxicological information, the information on the physical properties of the chemicals, and information that relates to the risk that would be attendant with the manufacture or use of the substance, particularly the potential for exposure or the controls that the manufacturer intends to apply.
2) Following such initial assessment, should all new chemicals be subject to testing requirements as outlined on pages 12 - 16 above?	Chemical structure and relationship to known carcinogens should only be one criteria for deciding to test a chemical and the decision to test should be for short term and not for animal bio-assays. The latter decision requires many other warnings or suggestive observations. It is our view that ideally all chemicals would be subject to appropriate tests to enable regulators, manufacturers and users to be absolutely certain of the level of hazard or lack thereof posed by all substances that are in commerce. However, recognizing the limitations on resources, particularly in the Province of Ontario, but also throughout the world, that can be applied to such data generation, we feel that a requirement that all new chemicals be subject to various testing requirements would be too costly for industry to bear, would generate too much information for the Ministry to review, and could not be accomplished with the resources in the Province of Ontario. Thus, we recommend that in the first instance, the manufacturer evaluate the potential toxicity of a substance and conduct a risk assessment that is appropriate to the nature of the substance being manufactured and share this risk assessment with the Ministry. Where the Ministry believes that additional testing or additional information needs to be obtained from sources other than testing, it should, on a case-by-case basis, advise the manufacturer or importer

REPORT TEXT	COMMENT
	of its views. In this way, a review of all chemicals will be possible but the testing resources need be applied only to those chemicals that cause concern to the Minister.
29. Issue #5 - Testing Procedures 1) Should a standard testing program be developed by the Ministry in consultation with the Advisory Committee?	The Ministry should not adopt a standard testing program. Any testing program must be carefully constructed to provide the greatest amount of new information at a practical expense to supplement the information that is already available on the particular substance. Flexibility and professional judgement are the keys to such a program, so rigid testing programs would be very inefficient. Instead, we recommend that the Ministry permit the manufacturers to develop and propose a test scheme for a substance where the Ministry requires additional information.
2) If such a program were to be developed, should it incorporate any or all of the following requirements: a) Where long term animal tests were required, should the procedure outlined in the National Cancer Institute (USA) "Guidelines for Carcinogen Bio-assay in Small Rodents", 1976, be followed?	
b) Where required, should a minimum of two appropriate short term tests be conducted on a substance?	Again, flexibility and professional judgement must be exercised, as one or more of a list of short term tests may be inappropriate for a particular substance. Perhaps a greater number of tests would increase the knowledge of a chemical's behaviour, but the particular circumstances of each situation should be considered before engaging in a program. It is important that test methodologies be scientifically sound and validated.
c) Should such tests be carried out on commercial samples of chemicals rather than on purified preparations (or in addition to)?	Generally, the substance should be tested in the form in which it is to be sold; however, it may be preferable to test a purified sample depending on what is known about the activity of the impurities.

REPORT TEXT	COMMENT
3) Where it is determined that a Category I substance is needed and that no suitable substitute is available, should its use be permitted, with the requirement that there be no detectable exposure of the workforce, or should permissible exposure limits be set?	It is our belief that acceptable exposure levels for carcinogens can be determined, below which there will be no observable excess of cancer. Various methods of predicting such a level exist and various information may be considered in making such an assessment. No observed effect levels and dose response relationships in animal bio-assays and results of human epidemiology studies are the principal types of information that can be used in making these determinations. If these exposure levels can be established, occupational uses should be permitted.
4) Should Category II substances be treated as suspect carcinogens? 5) Should permissible exposure limits be set for Category II substances?	With regard to Category II substances, whether or not these substances should be treated as suspect carcinogens will depend on the final definition of what a Category II substance is. If Category II turns out to be a "catch-all" classification which merely indicates that there may be concern about the substance but that concern cannot be resolved, or if this category also includes substances about which there is little basis for concern, but again little information is available, all Category II substances should not be treated as suspect carcinogens. In such cases, the treatment of the substance should be done on a case-by-case basis and the exposure limits based on potential for carcinogenicity and toxic effects should be employed where there is evidence or a reason to believe that exposure limits are needed.
6) Should the appropriate standards for Categories I and II substances be met through the use of engineering and work practice controls? 7) Should the use of personal protective equipment be reserved for maintenance purposes and for emergency use only?	Where exposure limits are established for substances in Categories I, II or III, based on the potential toxicity of such substances, we would recommend that the workers be protected through the use of cost-effective engineering controls augmented as necessary by personal protective equipment and/or work practices. It is our view that one needs to look at all methods of protecting employees and determine which methods are most appropriate for a given situation, rather than requiring in all cases, engineering controls or in all cases, work practice controls or the use of personal protective equipment. We do believe that the use of personal protective equipment

REPORT TEXT	COMMENT
d) Should the formal testing requirements, both for long term animal tests and for short term in vitro tests, established by the Ministry, be reviewed every three years?	As discussed above, the Ministry should not adopt formal testing requirements.
30. Issue #6 - The Classification of New Chemicals Should all new substances be placed in Categories I (carcinogens), II (suspect carcinogens) or III (non-carcinogenic) according to the criteria set out on pages 12 - 16 above?	We believe it would be desirable to be able to classify all chemicals, not just new chemicals, in Categories I, II or III, but we believe that particularly with new chemicals, most will be included in Category II because there will be inadequate information to definitively determine that they are carcinogenic to humans or that they are, without reservation, non-carcinogenic to humans. Thus, we agree in principle, that the effort should be made, but believe that the outcome in most cases will be a decision that there is inadequate information to make a definitive judgement. In the absence of such information, we feel that it would be unfair to the manufacturers of new substances, to declare these are suspect carcinogens.
31. Issue #7 - The Control of New Chemicals	
1) Where a substance is placed in Category I, should its use be regulated?	We agree that when a substance is determined to be carcinogenic to humans, its use should be regulated.
2) Where a suitable substitute for a Category I substance is available for one or more uses, should occupational exposure to the Category I substance be permitted for those uses?	Where a substance is classified in Category I and for social, economic or technical reasons, it is determined that the substance should be manufactured and/or used, then occupational exposure below harmful levels should be permitted. Substitution is a very complex matter. Very rarely can one chemical substance be substituted directly for another. Variations in chemical structure, reactivity, reaction products, and physical properties may make potential substitutes unsuitable in specific processes. Because of these highly complex considerations, it is unlikely that the Ministry could predict or determine if a potential substitute is in fact, suitable. For this reason, determinations of substitution should be left to the user.

REPORT TEXT	COMMENT
	may be appropriate in most instances in a maintenance situation, in emergency situations, or where minor and intermittent exposures may occur which do not justify the use of engineering controls. In summary, we believe that the approach to protection of the worker should be flexible and be based on all factors surrounding the potential for exposure. By following this approach, you achieve the most cost effective solution.
8) Should suitable epidemiological surveillance be maintained of workers exposed to Categories I and II substances?	As discussed under Issue #10, provision for prospective epidemiology for all chemical exposures is totally impractical. We do believe it appropriate for employers to maintain for a significant number of years sufficient records to identify employees, their work assignments and any chemical exposure data that may be obtained in the course of the employee's work.
9) Should the use of Category III substances be permitted without surveillance or restrictions unless such measures were required for other purposes?	We do not believe that any substance manufactured in a workplace should be used without any surveillance or restriction. However, where there is no indication of either carcinogenicity or other toxic effects, such surveillance could be used at a minimal level.
32. Issue #8 - The Testing and Classification of Chemicals not Considered New	
1) Should the Ministry, in consultation with the Advisory Committee, determine which of the substances on the EPA list or currently in use in Ontario, have not been adequately assessed for their potential carcinogenicity?	The Ministry should, in consultation with an appropriately staffed advisory committee, determine and establish priorities for review of the substances that are either on the EPA list or currently in use in Ontario for potential carcinogenicity. However, under the US law, EPA also reviews the status of chemicals that are on its inventory and the Province of Ontario could benefit by coordination with the US EPA to determine for which substances a determination of carcinogenicity has been made, for which substances a determination that they are not carcinogenic has been made, and which substances are currently scheduled to undergo additional carcinogenicity testing. With this information in hand, Ontario can determine which other substances should be evaluated and utilize the findings of the US EPA in reviewing the carcinogenicity of these substances.

REPORT TEXT	COMMENT
2) Should priorities be set for testing of such substances?	We support the committee recommendation that priorities be set for testing of substances. This should be done in conjunction with an overall review which would eliminate from the priority list, those substances where adequate testing has already been done.
3) Where it is considered necessary to test a substance currently in use in Ontario, should the cost of such testing be borne by the manufacturer?	We believe that in many instances it is most practical to have the cost of testing borne by the manufacturer (regardless of country of origin). However, this standard should be applied flexibly where more than one manufacturer is in existence or the Ministry must look to those operations which contribute most to exposure. Where one manufacturer has controlled exposure to a very low level, while another has not, the manufacturer who has taken the responsible position should not be forced to bear the same financial burden relative to testing as the manufacturer who has not acted as responsibly.
4) Where a chemical which is not considered new, is to be used in a newly constructed workplace, should it be automatically subjected to the same testing and classification procedures as employed for new chemicals?	Where a chemical which is not considered new is to be used in a newly constructed workplace, it should not be automatically subjected to the same testing and classification procedures as employed for new chemicals. The most efficient way for the Ministry to implement a carcinogen assessment program would be to systematically review all of the existing chemicals being manufactured or used in Ontario and not interrupt this review process simply because a chemical is manufactured at a new facility. However, where a chemical has been targeted for review and the new manufacture would pose significant potential additional exposure to the workforce, it may, in those circumstances, be reasonable to accelerate the review of such chemical. However, to do this with all chemicals to be employed in a newly constructed workplace, as indicated above, would be anticompetitive, would place additional burdens on new industrial efforts and could result in reduced construction of new industrial facilities in the Province of Ontario.

REPORT TEXT	COMMENT
5) Should the Ministry make a systematic attempt to have the substances on the EPA list and those currently in use in Ontario properly categorized, according to the classification system outlined above, within a period of five years, making full use of information developed in other jurisdictions?	As we indicated above, the Ministry should make a systematic attempt to review those substances currently in use in Ontario for not only carcinogenicity but other adverse health effects. This review should include a review of known information and a prioritization based on the degree of exposure and the potential to cause harm to the workforce for all such substances. However, the resources of the Province would not be capable of concluding such review within a period of five years, much less completing classification of all such substances within five years.
33. Issue #9 - The Control of Chemicals not Considered New	
1) Where a chemical, not considered new, is placed in Category I, where it is sufficiently beneficial to justify its considered use and no suitable replacement is available, should it be treated as follows: a) When used in a new plant, should it be subjected immediately to the same regulatory controls as are employed for new substances? b) When used in an existing plant, should it be subjected immediately to appropriate regulatory control?	With regard to a substance that is placed in Category I, it should not matter whether it is employed in a new plant, whether it is employed in an existing plant, or whether it is employed as a new substance in an existing plant. The Ministry should implement a program which would assure that the risk from such substance would be controlled. Thus, in determining what type of regulatory control should be employed, the Ministry would have to consider both the potency and the exposure of the substance, assuming that it had satisfied itself as to the carcinogenicity of the substance.
2) Where a chemical, not considered new, is placed in Category II, should it be treated as follows: a) When used in a new plant, should it be subjected immediately to appropriate regulatory controls? b) When used in an existing plant, should it be subjected to somewhat less stringent regulatory controls for an initial period?	Where a chemical is not considered new and is in Category II, it should not matter whether it is used in a new plant or in an existing plant in terms of the type of regulatory controls that are to be applied. The Ministry must determine what level of protection is necessary to assure the safety and health of the employees potentially exposed to the substance and recommend promulgation of regulations according to this standard. In some instances, it may determine that the technology that is available for new plants is not available or is not economically feasible to install in existing plants and may require engineering controls rather than protective equipment for new construction, but the basic issue

REPORT TEXT	COMMENT
	should be the protection of the employees and to ensure that adequate steps are taken to assure that. In any event, the determination should be done on a case-by-case basis.
3) After an initial period of five years, should all users of chemicals which are not considered new, be required to meet the standards set for new chemicals, regardless of whether the substances are to be used in new or existing plants.	As indicated above, establishment of a period such as five years to complete reviews, or to require that all chemicals meet certain standards, in view of the large number of chemicals that are employed in industry, is not a reasonable approach. The Ministry should review the chemicals that are in commerce and are manufactured in the Province of Ontario, should establish priorities for review and conduct such reviews thoroughly and promptly. In this way, all chemicals will be dealt with based on their potential to cause harm and decisions with regard to whether such chemicals should be controlled or not should be made on a case-by-case basis after a study of all available facts. To establish a period such as five years to complete this task would unduly burden the Ministry and would be doomed to fail.
34. Issue #10 - Epidemiologic Surveillance	
1) Should the Minister ensure that appropriate epidemiologic surveillance be provided where individuals are known to have been exposed to established or suspect carcinogens?	If epidemiologic studies will increase the knowledge of a substance's toxicity, and the data essential to a proper study are available, the Minister should encourage such studies.
2) Should employers be required to establish group and individual exposure records suitable for epidemiologic surveillance?	Employers should maintain exposure records that they may develop for eventual use in epidemiologic studies, however, employers should not be put to the extraordinary task of creating a prospective cohort and data base for exposure to any and all chemicals on the off chance that an epidemiology study may at some future date prove desirable.
3) Should the Minister seek to ensure that appropriate resources are made available to the Ontario Cancer Treatment and Research Foundation in order to guarantee continuance of the Ontario Cancer Registry?	We feel strongly that there should be continued support from all sectors, government and private alike, to guarantee continuance of the Ontario Cancer Registry. It is an important tool for doing epidemiological studies in Ontario and an important resource base for Statistics Canada for use in Canada-wide studies.

REPORT TEXT	COMMENT
35. Issue #11 - The Provision of Information to the Workforce and to the Public 1) Should the Ministry ensure that members of joint health and safety committees, or members of the workforce where no committees are established, are provided with information, not only on potential hazards, but also concerning the chemical structure of any new substance, regardless of whether it is considered by the employer to be safe?	We support the conclusion of the Advisory Panel that workers should be informed of the hazards of substances that are encountered in the workplace. Where necessary, such workers can be apprised of the chemical structure of the new substance. However, in most cases, this is not as important as informing the workers of the hazards that substances may pose, the manner in which the employees should protect themselves from the hazards and the procedures to be employed in the case of an emergency involving the substance. Certainly, if there is a health question involved, the employee and his physician should be advised where necessary of the name or structure of the substance. However, in view of the proprietary nature of many industrial operations, this right on the part of the employees and obligation on the part of employers should be tempered with a requirement that the information be maintained as a trade secret unless it is necessary in the interest of public health to make a disclosure.
2) Should the Ministry establish a procedure to ensure that details of the chemical structure and health effects produced by a new substance are available to the joint health and safety committee (or the workforce), in the event that management fails to provide this information?	We believe that the communication between employer and employee should not be disturbed by involving the Ministry. There should, perhaps, be a mechanism under which employers and employees could turn to the Ministry for a determination as to whether or not, in a particular instance, the identity of a substance need be disclosed. However, it is anticipated that these instances would arise very seldom if the Ministry would establish rules providing for protection of trade secrecy and limit the use of information concerning chemical identity by an employee or a union representative, to a determination of whether or not such substance poses a hazard under its conditions of manufacture or use. In short, we do not favour an absolute right of the Ministry to disclose chemical identity where management fails to provide this information on a routine basis. Furthermore, we believe that Section 14.2.c of the Occupational Health and Safety Act adequately deals with hazard notification.

REPORT TEXT	COMMENT
3) Should the Minister urge the government of Canada to work with the Canadian Centre for Occupational Health and Safety to develop a labelling and colour-coding system which would alert users and members of the workforce to the presence of a carcinogen or suspect carcinogen in any substance to be used?	Du Pont Canada Inc. supports the development by a federal-provincial task force, of a performance oriented workplace hazard communication system in which not only labelling but also the use of Material Safety Data Sheets and training programs comprise the elements of a system which would be used to notify and train individuals of the hazards related to chemical substances in the workplace. In such a system, it may or may not be appropriate to refer to the existence of suspect or proven carcinogens present in chemical products depending on the actual exposure potential and potency of the substance in question.
4) Should the Minister make available to the public an index of new substances showing the categories in which they have been placed? Should the data base which had led to this categorization also be made available for the public scrutiny?	We do not favour having the Minister make available an index showing categories in which substances have been placed, since with new substances there will very seldom be sufficient information to make a definitive finding and most substances will fall into a category which will in essence say that there is not adequate information to reach a decision, but that certain protective measures should or should not be taken. Thus, to publish a list could result in blacklisting a substance unnecessarily and reducing the possibility of successful commercial introduction of a substance where there is no serious cause for concern but in which the Ministry cannot make a definitive finding. This could have a chilling effect on innovation and new product introduction in the Province and should be discouraged as an unnecessary activity. Certainly, substances which have been categorized as being carcinogenic or substances that have been categorized as being non-carcinogenic should be disclosed, perhaps in the form of a list, but this should not be done until a complete review of the substance has been made.

REPORT TEXT	COMMENT
5) Should the confidentiality provisions of Section 34 (1)(b) of the Act apply in the case of carcinogens, or should there be full disclosure of all available information to the workforce and to the public?	We believe that the confidentiality provisions of Section 34(1)(b) of the Act should apply.
36. Issue #12 - Penalties for Non-Compliance with the Regulation	
Should an employer who introduces a known or suspect carcinogen into the workplace and fails to meet acceptable standards be liable to a penalty in excess of those currently available under Section 37(1) of the Occupational Health and Safety Act?	We believe that penalties in excess of those currently available under Section 37 (1) of the Act are not warranted.
37. Issue #13 - Research Should provision be made for the relaxation of the regulatory requirements in order to permit research in the following areas: 1) research targeted toward the development of new chemicals? 2) medical research involving the use of carcinogens for scientific or therapeutic purposes?	Industrial and academic research and quality control laboratories, unlike most industrial workplaces, typically use large numbers of substances in very small quantities for short periods of time. Because of these differences, application of many of the requirements of a carcinogen control regulation designed for an industrial workplace would be inappropriate for laboratories. A more satisfactory approach would be the exemption of laboratories from industrial workplace regulations in deference to use of general guidelines for prudent laboratory practice. Such guidelines were recently published by the National Research Council of the United States, Prudent Practices for Handling Hazardous Chemicals in Laboratories, National Academy Press, Washington, D.C., 1981. The NRC publication provides general guidelines for the safe handling and disposal of toxic substances in laboratories and we highly recommend this one set of guidelines versus all other chemical specific regulations.

ENERGY AND CHEMICAL
WORKERS UNION

SYNDICAT DES TRAVAILLEURS
DE L'ENERGIE ET DE LA CHIMIE

R. W. STEWART
Secretary-Treasurer
Secrétaire-Trésorier

317 Adelaide Street South, Suite 2
London, Ontario N5Z 3L3
(519) 685-0310

September 30, 1982

Office of the Chairman
Advisory Council on Occupational Health
and Occupational Safety
400 University Avenue
Toronto, Ontario
M7A 1T7

Dear Sir:

Enclosed please find the submissions of the Energy and Chemical Workers Union with respect to the Discussion Paper on the Control of the Work Place Carcinogens.

Yours very truly

Daniel Ublansky

Daniel Ublansky
Legislative and Health
Coordinator

DU:gas
Encls.

Energy and Chemical Workers Union

September, 1982

INTRODUCTION

Although estimates of the dimensions of the problem of occupational cancer vary, there is no argument with respect to the preventability of all deaths due to exposure to carcinogens. As the discussion paper prepared by the Advisory Council on Occupational Health and Safety points out:

"*. . . cancer can be prevented by controlling exposure to carcinogens and [that] such control* is *feasible.*"

Given these two threshold facts there can really be no doubt about the need for control and regulation of carcinogens wherever they are found. The only issue is the degree of regulation and control.

For the most part labour organizations have taken the position that no one should be exposed to the potential risk of developing cancer, irrespective of the benefits to society produced in the course of that exposure. The concept of "acceptable risk" when one is dealing in human life is simply not appropriate.

The discussion paper in its framing of the "Issues for Consideration" assumes that the zero risk argument will be rejected by policy-makers. The questions raised are obviously aimed at fleshing out the details of a regulatory program of control of suspected work place carcinogens rather than elimination thereof. As a result, our response to certain questions will probably not be helpful since we continue to cling to the notion that it is immoral to gamble with other people's lives.

With that caveat, the following represents our contribution to the "Issues for Consideration" raised by the Advisory Council.

ISSUES FOR CONSIDERATION

ISSUE #1 — National and International Coordination and Cooperation in the Control of Carcinogens

1. We would certainly support efforts to obtain federal government assistance in the financing of individual provincial initiatives and the establishment and coordination of a nationwide carcinogen program. This is a national problem which affects all Canadians and should be treated as such.

2. Obviously, any national program of this type should give a high priority to assembling and coordinating all available data with regard to the carcinogenicity and potential carcinogenicity of chemical substances.

3. The dimensions of the problem extend well beyond national and provincial borders, and solutions ought to be sought from the broadest possible base. The differences in approach that are observed between provinces are no less frustrating than those which exist between countries. Anything which promotes a more uniform attack upon the issue of work place carcinogens ought to be encouraged.

ISSUE #2 — Advisory Committee(s)

The establishment of an advisory council on the regulation of carcinogens does not strike us as particularly useful for a number of reasons. Firstly, there is little evidence that such committees have any major impact on government policy. Unless there is reason to believe that committee recommendations will be acted upon, then the creation of the committee would be pointless.

More fundamentally, perhaps, the creation of an advisory committee would provide the government with a form of insulation from contact with the parties directly involved. We feel that it would be preferable to have an open consultative process whereby all parties have equal access to the decision-makers.

ISSUE #3 — Reporting Requirements for New Chemicals

1. All manufacturers should be required to report any evidence of possible carcinogenicity of any chemical, new or otherwise, to the Minister.

2. Although the discussion paper concludes that "it is generally considered impractical to attempt to regulate substances which are to be used in very small quantities", there is no specific indication therein as to why this is so. If a manufacturer has evidence of possible carcinogenicity of a chemical, then there should be a legal requirement to advise the Minister. Such a requirement ought not to be qualified in any way.

ISSUE #4 — Testing Requirements for New Chemicals

1. There would be little point in introducing reporting requirements with respect to the possible carcinogenicity of chemicals unless that is supported by regulations calling for testing of such chemicals. It would have seemed more logical to have raised the issue of testing before that of reporting. In this regard, the discussion paper seemed somewhat unclear in its position.

2. In our view, testing should be the first step in the process and should not be discretionary. If it becomes a matter of opinion whether or not testing is necessary, then the potential for abuse is created. If exceptions are to be made, the onus of establishing the basis thereof should be on the manufacturer.

ISSUE #5 — Testing Procedures

1. Undoubtedly there is a need for a standard testing program to be developed with respect to the chemicals used in industry.

2. The recommendations of the Special Advisory Committee on carcinogens concerning testing procedures would seem to be a reasonable starting point given the present state of knowledge.

ISSUE #6 — The Classification of New Chemicals

On the understanding that Category I classification is based upon long-term animal testing as well as human cancer evidence, we would support the classification system as outlined in the discussion paper.

ISSUE #7 — The Control of New Chemicals

1. Category I substances should definitely be regulated.

2. Where a suitable substitute for a Category I substance is available for one or more uses, occupational exposure to that substance should not be permitted for those uses.

3. Where suitable substitutes are not available for a Category I substance, there can be no justification for the exposure of anyone to that substance. The only effective means of preventing cancer deaths is to eliminate the risk. It is recognized that TLVs may not protect all persons exposed to carcinogenic substances. Therefore, the only way to ensure the health of workers and others exposed to a Category I substance is to eliminate exposure.

4. For purposes of classification, it may be desirable to recognize Category II substances as suspect carcinogens, but for purposes of regulation and control, there can be no rational basis for distinction between Category I and II.

5. There is no more compelling rationale for setting exposure limits for Category II substances than there is in the case of Category I. An educated guess is still no more than just that — a guess. To gamble with people's lives and health in this manner is totally immoral.

6.-8. In view of our position with respect to the elimination of exposure to Category I & II substances, the answers to these questions are obvious.

9. Although there may be no justification for the restriction of Category III substances, it is possible for the test results to be incorrect. Thus some follow-up is necessary once the initial categorization has taken place. A properly structured surveillance program would be a useful means of verifying initial judgments. In the absence of this, a program for the testing of chemicals not considered new should include an ongoing assessment of Category III substances.

ISSUE #8 — The Testing and Classification of Chemicals Not Considered New

1. The Ministry should definitely identify those substances in use in Ontario which have not adequately been assessed for their potential carcinogenicity.

2. Although the discussion paper does not deal with possible criteria for the establishment of priorities, it is reasonable to anticipate the necessity for such priorities.

3. The cost of such testing should be borne by the manufacturer.

4. It would seem to us that testing should be based upon the priorities established rather than on the random occurrence of the opening of a new work place. It may well be that prudent manufacturers who are aware of the

potential for regulation and control would choose to do the appropriate testing prior to such a new undertaking in any event.

5. The Ministry should definitely complete the task of categorization within a period of five years.

ISSUE #9 — The Control of Chemicals Not Considered New

1. As indicated above, we do not consider any chemical, new or otherwise, to be "sufficiently beneficial" to justify continued exposure once it has been identified as a potential carcinogen. Consistent with that approach, we could not support any distinction based upon whether the substance is used in a new or existing plant.

2. We see no justification for differentiating between the handling of Category I and Category II substances or new and existing plants.

3. Again we have some difficulty supporting any policy which permits differing levels of exposure depending upon where you work. Once a substance has been identified as Category I or II, regulation and control measures must be applied wherever exposure takes place.

ISSUE #10 — Epidemiological Surveillance

1. The Minister should ensure that appropriate epidemiologic surveillance be provided where individuals are known to have been exposed to established or suspect carcinogens.

2. Employers should be required to establish group and individual exposure records suitable for epidemiologic surveillance.

3. The Minister should seek to ensure that appropriate resources are made available to the Ontario Cancer Treatment and Research Foundation in order to guarantee continuance of the Ontario Cancer Registry.

ISSUE #11 — The Provision of Information to the Work Force and to the Public

1. There is no question that the Ministry must ensure that members of the joint health and safety committees, or members of the work force where no committees are established, are provided with information, not only on potential hazards, but also concerning the chemical structure of any new substance. Workers must have the best possible information so that they can decide for themselves whether a substance is safe.

2. The Ministry should establish a procedure to ensure that details of the chemical structure and health effects produced by a new substance are available to workers. This procedure must be designed to ensure compliance by all employers. If it is left to workers to try to provide the enforcement mechanism, then it is inevitable that, given the number of unorganized work places in this Province, many employers will be able to avoid compliance.

3. Cooperative efforts to introduce a labelling and colour-coding system to identify carcinogens should, of course, be encouraged.

4. It is essential that an index of new substances showing the categories in which they have been placed, and the data base which has led to this categorization, be made available for public scrutiny.

5. There is no justification for the withholding of information on matters of public health. Proprietary interests must always give way when a legitimate public interest is at stake.

ISSUE #12 — Penalties for Non-Compliance with the Regulation
The introduction of known or suspected carcinogens into the work place without due regard for existing regulations or the protection of the health of those exposed thereto is a serious crime which ought to be penalized accordingly. Present fines do not reflect this and amount to nothing more than license fees to maim and kill.

ISSUE #13 — Research
If exceptions to regulatory requirements are proven to be necessary for purposes of research, then relaxation of regulatory requirements may be permissible. However, this ought not to be used as a means of exposing those involved to unconscionable risks.

Environment Canada
Environnement Canada

Environmental Protection
Protection de l'environnement

Ottawa, Ontario
K1A 1C8

SEP 27 1982

Dr. J.F. Mustard
Chairman
Advisory Council on Occupational Health
and Occupational Safety
400 University Avenue
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

I would like to thank you for the opportunity of reviewing your Report on Carcinogens and the discussion paper on Control of Workplace Carcinogens. I found them both most informative.

While it is not our mandate to deal directly with human carcinogens, particularly with regard to the workplace, we do have the responsibility within the federal government for ensuring co-ordination of efforts directed at the control of toxic chemicals.

We are most interested in two of the areas that you address: the development in Canada of testing procedures, particularly as these might compare to and be co-ordinated with international efforts, and the development of legislation to deal with premanufacturing data for new chemicals. The following points will, I believe, be of interest to you.

1. There already exist a number of international data collecting and assessing processes pertinent to your area of interest.

2. Work is progressing on the development of interpretation guidelines for premanufacturing data for new chemicals. This is again an international effort in which we are co-operating.

...2

Canada

3. In general, testing of chemicals, again being worked on internationally, will follow a cascading scheme based largely on cost and effectiveness. Carcinogenicity is the final testing phase because it is the most costly and time-consuming and would be completed only after a chemical failed to pass other tests. There would be two separate carcinogenic screens at a preliminary stage of the cascade.

4. Many of these considerations are being applied to existing chemicals, but there the problem is so immense that we must all co-operate to achieve the required ends within any useful time frame.

Should you be interested in details of these international efforts, Dr. J.E. Brydon of the Contaminants Control Branch (819-997-1499) would be pleased to discuss them with you. I would also encourage you to send your report to the Department of National Health and Welfare for comment, although I imagine that you have already done so.

You may be interested to learn that the Department of the Environment, the Department of National Health and Welfare, and the Canadian Council of Resource and Environment Ministers are sponsoring a "New Chemicals Workshop" to take place in Toronto on November 3, 4 and 5, 1982. This event has the support of the Federal/Provincial Advisory Committee on Occupational and Environmental Health and the Canada Centre for Occupational Health and Safety. The aim of this workshop is to exchange information about what is already under way internationally, federally, and provincially, and to discuss what needs to be done further, in the expectation that the federal Environmental Contaminants Act will be amended to deal more adequately with new chemicals. Dr. Donna Brown of the Ontario Ministry of Labour is a member for the Steering Committee for the Workshop.

.../3

Thank you again for keeping us informed of the developments. I look forward to our continuing co-operation on these issues, which are of concern to us all.

Yours sincerely,

for
R. W. Slater
Assistant Deputy Minister

c.c Dr. A.B. Morrison

FALCONBRIDGE

October 26, 1982

Advisory Council on
Occupational Health
& Occupational Safety
Office of the Chairman
400 University Avenue
Toronto, Ontario
M7A 1T7

Attention: J. F. Mustard, M.D.
Chairman

Dear Sir:

Please find enclosed our evaluation of the Discussion Paper on "The Control of Workplace Carcinogens".

Sincerely,

R. Caldwell (Mrs.)

for A. G. Cecutti, M. D.
Medical Director

AGC:rc
Encl.

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Falconbridge Limited

October, 1982

Preface

Bill Andrews writing for the National Safety Council in The Shape of the 1980's on ethics, states as follows:

> *"Do not begrudge these men and women their disagreements. Do not rebuke the warmth of advocacy. The safety movement would be poorer, less effective, a less moral enterprise than it is if we sought to conceal the reality of our differences of opinion. If safety is not worth arguing about, what on earth is!"*

It is in this spirit that we reply to your request for input to your advisory memorandum to the minister. That our reply does not stay within the confines of your mandate should have been expected.

Table of Contents

1. General Comments on Regulatory Activity and Specific Carcinogenicity

2. Discussion of, and Comments on, the Advisory Council's Paper: "The Control of Workplace Carcinogens"

3. Issues for Consideration
   — Questions & Answers

1. General Comments on Regulatory Activity and Specific Carcinogenicity

The accompanying document by the Advisory Council "Report of the Special Advisory Committee on Carcinogens" is acknowledged by the writers as an excellent scientific paper on the evaluation of cancer in Ontario.

This discussion paper on "The Control of Workplace Carcinogens", we feel, is lacking in definition, recognition, evaluation and perspective.

We will address each of these categories in our response.

Definition
The word "carcinogen" is frequently misused, and defining the correct terminology at the outset would dissipate some of the neurotic fear connected with the word.

The National Research Council[1] provides the following definitions: "A *malignant neoplasm* is composed of a population of cells displaying progressive growth and varying degrees of autonomy and cellular atypia. It displays, or it has the capacity for, invasion of normal tissues, metastasis, and causing death to the host."

"*Benign neoplasms* are a less autonomous population of cells and exhibit little or no cellular atypia or invasions of normal tissues and do not metastisize."

Mutagen. "A chemical or physical agent that is capable of producing a heritable change in genetic material. These changes may be either point mutations or chromosomal mutations and can occur in either somatic or germ cells."

Human Carcinogen. "An agent, which may comprise a combination of chemicals, is carcinogenic in 'people' if it increases the incidence of malignant neoplasms in humans to levels that are significantly higher than those in a comparable group not exposed to the same agent."

NIOSH's preface on Suspected Carcinogens reports that its publication does not indict a substance as a human carcinogen, but that a substance has neoplastic or carcinogenic effects.

The general, accepted, specific classification is as follows:

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[1] National Research Council, *Drinking Water & Health*, National Academy of Sciences, Washington D.C. (1977)

Test	Results	
In Vitro	Negative →	Non Mutagenic
	Positive------	Mutagenic then suspected animal carcinogen
In Vivo	Negative →	Non Carcinogenic
	Positive------	suspected → animal carcinogen human carcinogen
	↓	
Epidemiology	Negative →	Non Human Carcinogen
	Positive ↓ Human Carcinogen	

Many people interchange this terminology and incorrectly call all phases as carcinogens rather than,

Mutagen (suspected animal carcinogen)
↓
Animal carcinogen (with at least 2 specific tests suspected human carcinogen)
↓
Human carcinogen (with epidemiology evaluation)

Recognition
Dr. W.D. Rowe in "An Anatomy of risk" Table 16.4 on Death Rate by Cause of Death shows cancer as a portion of the death rate to be 16.77% of all deaths per year in the USA. He further identifies Preventable Deaths in Table 17.8.

Table 16.4 Death Rate by Cause of Death

Class	Death Rate/100,000/yr	
Natural catastrophes		0.99
Man-made catastrophes		0.032-0.22
Common accidents (1972)		
Motor accidents	27.2	
Work related	6.8	
Home	13.0	
Public nonmotor vehicle	11.3	
Total		58.3
Disease (1969)		
Heart disease	367	
Cancer	160	
Stroke	103	
Pneumonia	31	
Diabetes mellitus	19	
Arteriosclerosis	16	
Total		696
Homicide, suicide, other		199
Total		954

Source: Accident Facts, 1973.

Table 17.8 Preventable Deaths

Cancer Type and Associated Factors	Expected Deaths	Preventable Deaths
Cigarette smoking: lung and some larynx	80,000	70,000
Alcohol		
Head and neck	7,500	5,000
Esophagus	6,000	
Industrial exposure		
Bladder	9,000	5,000
Liver	9,800	
High fat, low bulk diet		
Breast	30,000	5,000*
Colon and rectum	30,000	10,000
Other factors		
Uterine, cervix	7,500	3,000*
Melanoma, other skin cancer	5,000	1,500
Totals	184,800	99,500

* Achievable mostly through earlier diagnosis by application of known techniques. Figures are for 1974, as reported by Dr. Marvin A. Schneiderman, National Cancer Institute.

Dr. M.A. Schneiderman, National Cancer Institute, (Table 17.8) shows of the preventable deaths, only approximately 5% are due to industrial exposure in the US (1974).

When 16.8% of all deaths are due to cancer, and approximately 10% are industrial exposure, then industry would be responsible for approximately 1.7% of all deaths.

Control of workplace carcinogens should be examined from this perspective.

Dr. Philip Handler, US President of the Academy of Science, at the 11th International Congress of Biochemistry in Toronto (1979) stated: "World-wide attention is being drawn to environmental chemicals as being pivotal in causing cancer, but this is just not the case."

He also observed, "Furthermore, the death rate from cancer in North America is not much different from that in developing countries, which use neither chemicals nor energy to the extent that we do."

Dr. Philip Cole, M.D., Dr. P.H. and Professor of Epidemiology, Harvard School of Public Health, in his 1979 Gordon Richards Memorial Lecture, comments on a set of three bases usually advocated for emphasis on prevention of cancer as follows:

1. *Improvement of Cancer Therapies:* He believes dissatisfaction with excessively slow progress in the improvement of cancer therapies is ill-founded. He notes, "a strong argument can be made that cancer treatment has improved at a steady and reasonable pace."

2. *Cancer is Increasing and that Preventable Environmental Contamination is to Blame:* He notes, "this view is unsubstantiated and seems to rest mainly on that fact that the proportion of deaths due to cancer is rising."

Dr. Cole goes on to say, "In fact, as a generalization, absolute cancer mortality rates are nearly stable."

E.g. 1968 age adjusted mortality for W.M.* was 129/100,000 man yrs.
1976 age adjusted mortality for W.M.* was 133/100,000 man yrs.,

and he notes, "Cancers which are unrelated to smoking are stable, declining or rising only to an extent consistent with improved diagnoses, reporting and certification of the cause of death."

"There are many good reasons why it should be controlled. But, *it will prove counter productive in the long run to take a general environmental approach to cancer prevention when the principal causes of the disease are our individual, private forms of self-pollution and localized environmental factors*." (Authors' italics)

3. *Disenchantment with Viruses as Human Carcinogens:* Dr. Cole states, "This has shifted attention to chemicals as the causes of cancer and in particular to the workplace as the focus of adverse exposures."

---

*White Males

He notes that it would be unfortunate if virus research is not continued, as significant studies support that viruses are a part of the cause of cancer of the liver, of Burkett's lymphoma and of cancer of the cervix.

Edward J. Calabrese, Assistant Professor of Health at the University of Massachusetts, in Pollutants and High-Risk Groups, 1978, reproduces a graph from an English study of 9,975 men and women aged 35 to 69 to clearly support the conclusion that smoking is a more important factor in the development of respiratory disease than typical urban air pollution:

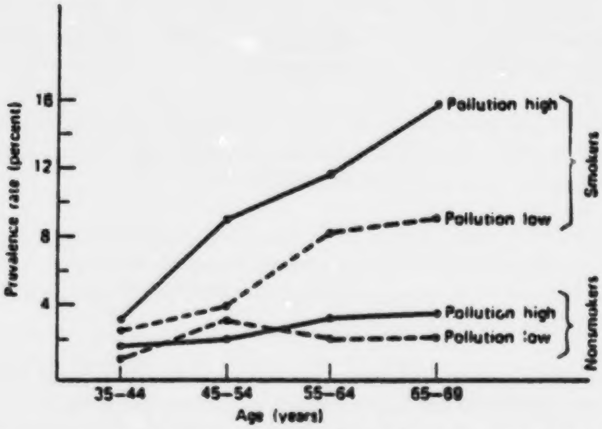

Figure 26. Age trends in respiratory disease in relation to smoking and air pollution. *Source.* Lambert (1970).

Calabrese, also in dealing with Dietary Patterns, reproduces risk ratios for oral cancer according to level of exposure to alcohol and smoking:

Table 22. Risk Ratios for Oral Cancer According to Level of Exposure to Alcohol and Smoking[a]

Alcohol per Day (oz)	Cigarette Equivalents per Day			
	0	Less than 20	20–39	40 or More
None	1.00	1.52	1.43	2.43
< 0.4	1.40	1.67	3.18	3.25
0.4–1.5	1.60	4.36	4.46	8.21
> 1.5	2.33	4.13	9.59	15.5

[a] **Risks are expressed relative to a risk of 1.00 for persons who neither smoked nor drank.**

Source. **Rothman and Keller (1972).**

This table demonstrates that the relative risk for 40 or more cigarettes is the approximate equivalent of > 1.5 oz. alcohol per day, but the ratio is approximately 3× the sum of those individual risks.
{E.g. (2.43 + 2.33) × 3 ≑ 15.5}

Calabrese notes that Jones & Grindon (1975) have derived a dose-response relationship for a variety of chemical carcinogens, and indicated the latency period shortens as the dosage increases according to an inverse-cube relationship.

Dr. Harry B. Demopoulos, Associated Professor of Pathology at New York University Medical Center, examined the U.S. National Cancer Institute's Third National Cancer Survey. He compared Detroit, Pittsburgh and Birmingham, where 40% of the work force is engaged in "dirty" industries (during 1969-1971), with four "clean" cities that are not industrialized: San Francisco, Dallas, Minneapolis and Atlanta; and found 8% less cancer in the three "dirty" cities.

The preceeding examples under *Recognition* are only a small segment of the vast amount of data available on cancer or related cause and effects vs. prevention of morbidity.

Evaluation

There are scientists such as Roe, Schneiderman, Handler, Cole and Calabrese producing information on human cancer statistics, evaluating those statistics to show that human cancer rates are generally stable and Dr. Cole notes, "principally caused by individual, private forms of self-pollution and localized environmental factors."

We have not introduced genetic disorders, nutritional deficiencies or hypersusceptibility as examples of other variables, but these, too, would have to be addressed in dealing with cancer in perspective.

It would appear a Socio Economic Impact Analysis should be done on all the causes of cancer to determine the most cost-effective approach to the reduction of cancer in Canada.

Perspective

Provincially, the Honourable Darcy McKeough, in November 1977, identified three basic components for a new economic 5-year development program:

1st – "curb public-sector growth . . . keep the system from consuming the money and human resources that private enterprise needs".
2nd – The system is "badly gummed up at the moment by over-regulation, featherbedding and misallocation of resources".
3rd – "We have to persuade industry . . . to concentrate more of their investments and future efforts in those areas where they can match the international competition."

Jack Donnan, Senior Economist, Ministry of the Environment, in February 1981, states, "The MOE and other provincial government agencies are now required by Cabinet Directive to assess the magnitude and incidence of the economic impact of any new regulatory activity or program."

He explains the economic tools and principle applied, "An explicit balancing of the benefits and costs of particularly costly and contentious regulatory actions and programs."

Also, "A clearer and more explicit specification of the distribution and incidence of the benefits and costs of new regulations. . . ."

Christine Lucyk, Analyst, Ministry of the Environment, in April 1981, speaking on economic significance of acid deposition notes that cost and benefits are not equated, but "rather that some sense of the relative magnitude of costs and benefits *is necessary to determine policy options*." (Author's italics)

These provincial government statements appear to agree with D.G. Kelley of the Federal Government in August, 1979 on perspective where he states, "In the recent past, society felt it could pay any price and accept any social or economic cost for a cleaner environment. This philosophy has run into the hard reality of competition with other social and economic objectives."

In Vancouver, on October 2, 1982, the reaction of the Provincial Health Ministers to the Federal Government's Canada Health Act was certainly interesting. For example:

- B.C.'s Health Minister, Neilson, stated that under the proposed Act, the Federal Government might set standards that the provinces couldn't meet, which might force them to cut programs they now offer.
- Quebec's Social Services Minister, Johnston, said, "What it means is more make work, more bureaucracy, more control. . . ."
- Ontario's Health Minister, Grossman, said the Federal Government should not interfere with Provincial jurisdiction and delivery of health care unless it could show the provinces were not doing an acceptable job.

These statements by the Provincial Ministers are interesting in light of your statements on Page 8 that "representation be made to the Federal Government, calling for assistance in the financing of individual provincial initiatives, and for the establishment and coordination of a nationwide program."

We, in the mining industry in Ontario, feel the same as the Provincial Ministers about this proposal for Regulation of Occupational Carcinogens, namely:

1. Your proposal would cause us to cut programs we are now working on (i.e. your priorities are not our priorities).

2. What this proposal means is more make work, more bureaucracy, more control . . .

3. We feel that Ontario's Health Minister should not interfere with our priorities in Occupational Health and Industrial Hygiene unless they can show the mining industry is not doing an acceptable job.

WE BELIEVE

We believe that burden of proof should rest with governments.

We believe that an economic impact assessment is required before a major rule is promulgated.

We believe that cancers in the workplace are a small percentage of cancer deaths and should be studied in total perspective.

We believe that guidelines rather than standards should be addressed for the mining industry.

We believe that costs for implementing guidelines/standards for existing plants be given special taxation incentives and support of government funds.

We believe that as stated by Herb Stokinger, writing in Science in 1971, that:

- Standards must be based on scientific fact, realistically derived and not on political feasibility, expediency, emotion of the moment or unsupported information;
- All standards, guides, limits and so on, as well as the criteria on which they are based, must be completely documented;
- The establishment of unnecessarily severe standards must be avoided; and,
- Realistic levels must be determined.

2. Discussion of, and Comments on, The Advisory Council's Paper: "The Control of Workplace Carcinogens & Suspect Carcinogens"

General
The Advisory Council, in their introduction to this section, have emphasized the use of techniques for assessing the potential carcinogenicity of a chemical. These techniques are known to the authors. The evalution of the results of this testing, and by whom, is of concern to the industry.

The IARC (International Agency for Research on Cancer) have reviewed 368 chemicals and industrial processes (September 1978) and found 221 chemicals or mixtures identified as carcinogenic to one or more animal species, but only 26 were identified as associated with increasing cancer in man. Of these 26, only 8 or 9 involve exposure to a large number of workers in the U.S.A. Careful evaluation of potential carcinogens is required before regulation.

Other examples of our concerns are given in the following comments on this section. These comments identify the statement, by page and line number, in your original text.

The subject of potential carcinogens, we believe, requires very careful evaluation by an independent scientific committee.

1. New Chemicals
Pg. 10, line 2: *"There appears to be general acceptance of the philosophy that all new chemicals should be screened and that if any are found to be carcinogens or potential carcinogens, their application in industry should be regulated."*

We agree that new chemicals should be screened, and that properly researched carcinogens should be subject to realistically derived standards.

The subject of potential carcinogens, we believe to be a separate subject, and should be considered separately. e.g.

a) Lead compounds have been reported positive in animal studies by at least four researchers, but the NRC report[2] on *"Airborne Lead in Perspective"* by Hammond et al. found lead poisoning is not associated with an increased cancer rate.

b) Nelson et al.[3] implicated Selenium as a carcinogen (in 1943), but Harr et al.[4] found no liver tumors in over 1,000 rats on a normal diet (in 1967) and recent information by Schrauzer[5] in *"Inorganic & Nutritional Aspects of Cancer"* (in 1978) suggests an anticancer effect of Selenium.

Pg. 10, line 6: *"Regulations for the control of carcinogens and suspect carcinogens, to be used in the workplace in Ontario, could be established by the minister after appropriate public discussion. In reaching his final decision*, the minister might wish to consult solely with ministry staff."

This practice is completely unacceptable to the mining industry. Our analysis indicates that SEIA (Socio-Economic Impact Analysis) is a must for a major regulation. Our answer to this statement is found under *Perspective* in our submission.

Pg. 10, line 10: *"Alternatively, he* might *supplement the advice provided by his ministry with opinions offered by an advisory committee or committees. . . ."*

The composition of an advisory committee should be strictly scientific, and if the minister feels he needs public input, it should be made under a separate committee.

Pg. 11 (4), line 8: *"To make recommendations to the minister with regard to the suitability of substitutes for known carcinogens."*

This statement assumes a zero exposure threshold. Animal research has shown that zero concentration is not necessary to protect workers. E.g. chlorine for protection of potable water supplies.

Pg. 12 & Chart, Pg. 31: *A. Identification & Classification*. These pages deal with classification of substances. We do not believe an advisory committee should be authorized to classify substances that prove negative (non-positive) in short-term tests as Category I. We believe only substances that are Positive in short-term tests, followed by two species animal tests that show positive, should be considered as Category I substances.

Pg. 14, line 11: *"that if members of the committee had* any doubts whatsoever *about the safety of a substance, the appropriate recommendation would be to place it in Category II."*

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[2] Hammond et al., "Airborne Lead in Perspective", National Research Council, Washington D.C., 1972
[3] Nelson et al., Cancer Research, 3, 230 (1943)
[4] Harr et al., Selenium in Biomedicine, Avi Publishers, Westport, Conn., 1967
[5] Schrauzer, Inorganic & Nutritional Aspects of Cancer, Plenum Press, New York, 1978

This evaluation smacks of subjective evaluation, and a single member would be allowed to place all substances in Category II using the "cover your ass syndrome".

Pg. 14, line 14: *"The criteria applied by the committee in recommending appropriate categories and regulatory controls, should be subject to periodic review by the ministry."*

The criteria applied by the committee should also be subject to scientific as well as ministry (political) review.

Pg. 17, last sentence: *"which might entail the imposing of a suitable financial penalty. Some have even considered the idea that offending parties should lose their protection . . . under the Workmen's Compensation Act. . . ."*

This statement smacks of intimidation. The US system has also used this approach, and the over-regulation has resulted in major court activity where only the lawyers gain, and the Occupational Health System loses.

2. Chemicals Not Considered New
Pg. 18, line 18: *"Expenses of such testing should be borne by the manufacturer of a substance currently in use in Ontario."*

It should be considered a ministry responsibility for proof of testing and cost to categorize the EPA list of chemicals. The EPA has been at this job for at least ten years, and with their huge budget have only been successful in categorizing approximately 50 substances per year. This would require massive effort and funding during a 5-year period as suggested.

The International Agency for Research on Cancer had only evaluated 368 chemicals and industrial processes by September 1978, whereas NIOSH have listed 2,415 suggested carcinogens.

Pg. 19, line 1: *"Where a chemical, which was not considered new, was to be used in a newly constructed plant, it should automatically be subject to the same testing and classification procedure as employed for new chemicals."*

This requirement would be a contentious regulatory action that is normally considered over-regulation. There can be no good scientific reason for it. If government is not able to regulate current operations with current knowledge, why regulate new industry out of existence?

Pg. 19, line 12: The application of this same rule for Category II substances appears to be a complete lack of understanding of relative risk and of the enormous work and cost of this requirement.

The U.S. Supreme Court has dealt with this subject, and ruled *the lowest feasible-level precept* was replaced by the courts *significant risk* concept before any regulating could take place.

3. Issues for Consideration

Issue # 1 — National and International Co-ordination and Co-operation in the Control of Carcinogens

Question 1: Should representation be made, through the appropriate channels, to the federal government calling for assistance in the financing of individual provincial initiatives and for the establishment and co-ordination of a nationwide carcinogen program, through agencies such as the federal Department of Labour, the Department of National Health and Welfare and the Canadian Centre for Occupational Health and Safety?

Answer: Representation should be made to the federal government for a cooperative study of a Socio Economic Impact Analysis of a cancer policy for Canada. The study should be all encompassing, and not limited to control of workplace carcinogens.

Question 2: As part of a national program, should the federal government or national agency be encouraged to give the highest priority to the objective of assembling and co-ordinating the available data from this and other jurisdictions, with regard to the carcinogenicity and potential carcinogenicity of chemical substances?

Answer: Yes.

Question 3: In establishing priorities for the testing of chemicals and in deciding upon appropriate regulatory controls for carcinogens and suspect carcinogens, should the Ontario Ministry of Labour work in close collaboration with international organizations such as the International Labour Organization? Should due regard be paid to international agreements such as the ILO 'Convention concerning prevention and control of Occupational Hazards caused by Carcinogenic Substances and Agents'?

Answer: No. This, too, should be part of 1).

Issue #2 — Advisory Committee(s)

Question:	Should an advisory committee(s) be established with the responsibility for advising the minister (or the ministry) on all aspects of the regulatory program for carcinogens? In particular, should the advisory committee make recommendations with regard to the appropriate categories and regulatory controls for chemical substances? Should the criteria applied by the committee be subject to periodic review by the ministry?
Answer:	The Advisory Committee should be an *independent* scientific panel with an emphasis on risk assessment; the consideration of negative as well as positive animal and human data; a close look at interspecies metabolic (physiological) differences. We recommend separating science from social and political arenas so that decisions will not be taken for administrative convenience rather than valid scientific reasons.

Issue #3 — Reporting Requirements for New Chemicals

Question 1:	Should the minister establish reporting requirements for full disclosure of the possible carcinogenicity of any new chemical to be introduced into the workplace in Ontario?
Answer:	Yes.
Question 2:	Should limited reporting requirements apply to new chemicals to be marketed in quantities of less than one tonne per annum unless, after an initial assessment, (see *Issue #4*) they were considered suspect?
Answer:	Yes; subject to the answer of *Issue #4*.

Issue #4 — Testing Requirements for New Chemicals

Question 1:	Should the Minister establish regulations calling for the examination of all new chemicals on the basis of their chemical structure and relationship to known carcinogens?
Answer:	Yes; subject to answer of Issue #1.

Question 2: Following such initial assessment, should all new chemicals (with the exception noted in #3 above) be subject to testing requirements as outlined on pages 12-16 above?

Answer: Yes; with the exception as noted on the comments on the report, pages 12 and 31.

Issue #5 — Testing Procedures

(For further details see pages 170-171 of the Report of the Special Advisory Committee on Carcinogens.)

Question 1: Should a standard testing program be developed by the ministry on consultation with the advisory committee?

Question 2: If such a program were to be developed, should it incorporate any or all of the following requirements:—

a) Where long-term animal tests were required, should the procedure outlined in the National Cancer Institute (USA) *''Guidelines for Carcinogen Bioassay in Small Rodents''*, 1976, be followed?
b) Where required, should a minimum of two appropriate short-term tests be conducted on a substance?
c) Should such tests be carried out on commercial samples of chemicals rather than on purified preparations (or in addition to)?
d) Should the formal testing requirements, both for long-term animal tests and for short-term in vitro tests, established by the ministry, be reviewed every three years?

Answer: All Sections: Yes (Scientific Committee only).

Issue #6 — The Classification of New Chemicals

Question: Should all new substances be placed in Categories I (carcinogens), II (suspect carcinogens) or III (non-carcinogenic) according to the criteria set out on pages 12-16 above:

Answer: Yes; subject to comments already made prior to the Issue Numbers.

Issue #7 — The Control of New Chemicals

If the classification scheme referred to in Issue #6 is thought to be appropriate, should the following measures be adopted:

Question 1: Where a substance is placed in Category I, should its use be regulated?

Answer: Only if adequately tested, and subject to further evaluation by epidemiology reports on the substance.

Question 2: Where a suitable substitute for a Category I substance is available for one or more uses, should occupational exposure to the Category I substance be permitted for those uses?

Answer: Yes. Substitutes should be subjected to cost/benefit analysis.

Question 3: Where it is determined that a Category I substance is needed and that no suitable substitute is available, should its use be permitted, with the requirement that there be no detectable exposure of the workforce, or should permissible exposure limits be set?

Answer: Permissible exposure limits should be set based on all specific evidence available.

Question 4: Should Category II substances be treated as suspect carcinogens?

Answer: Not on the basis of subjective analysis.

Question 5: Should permissible exposure limits be set for Category II substances?

Answer: Non-positive animal tests should exempt Category II substances from limits.

Question 6: Should the appropriate standards for Categories I and II substances be met through the use of engineering and workpractice controls?

Answer: Yes, for Category I; if limits are reasonable and attainable.
No, for Category II. Cost/benefit should be the evaluation to determine the need.

Question 7: Should the use of personal protective equipment be reserved for maintenance purposes and for emergency use only?

Answer: No. The individual's choice is subjective for protection based on needs and hypersusceptibility.

Question 8: Should suitable epidemiological surveillance be maintained of workers exposed to Categories I and II substances?

Answer: Yes, for Category I. Surveillance of Category II substance workers should be based on a specific request by the scientific committee. (The authors' concerns here are to prevent a major cost for a minimum benefit.)

Question 9: Should the use of Category III substances be permitted without surveillance or restrictions unless such measures were required for other purposes?

Answer: Yes.

Issue #8 — The Testing and Classification of Chemicals Not Considered New

Question 1: Should the ministry, in consultation with the advisory committee, determine which of the substances on the EPA list or currently in use in Ontario have not been adequately assessed for their potential carcinogenicity?

Answer: Yes, using a strictly scientific panel.

Question 2: Should priorities be set for testing of such substances?

Answer: Yes, with an independent scientific panel.

Question 3: Where it is considered necessary to test a substance currently in use in Ontario, should the cost of such testing be borne by the manufacturer?

Answer: No.

Question 4: Where a chemical which is not considered new is to be used in a newly-constructed workplace, should it be automatically subjected to the same testing and classification procedures as employed for new chemicals?

Answer: No.

Question 5: Should the ministry make a systematic attempt to have the substances on the EPA list and those currently in use in Ontario properly categorized, according to the classification system outlined above, within a period of five years, making full use of information developed in other jurisdictions?

Answer: This is too short a time period based on US experience.

Issue #9 — The Control of Chemicals Not Considered New

1. Where a chemical, not considered new, is placed in Category I, where it is sufficiently beneficial to justify its continued use and no suitable replacement is available, should it be treated as follows:—

Question a): When used in a new plant, should it be subjected immediately to the same regulatory controls as are employed for new substances?

Answer: No.

Question b): When used in an existing plant, should it be subjected immediately to appropriate regulatory controls?

Answer: No. The word "appropriate" needs adequate defining. The word "immediate" would depend on the relative risk.

2. Where a chemical, not considered new, is placed in Category II, should it be treated as follows:—

Question a): When used in a new plant, should it be subjected immediately to appropriate regulatory controls?

Answer: No.

Question b): When used in an existing plant, should it be subjected to somewhat less stringent regulatory controls for an initial period?

Answer: It would depend on its relative risk.

Question 3: After an initial period of five years, should all users of chemicals which are not considered new be required to meet the standards set for new chemicals, regardless of whether the substances are to be used in new or existing plants?

Answer: No. The SEIA should govern based on rational evaluation.

Issue #10 — Epidemiologic Surveillance

Question 1: Should the minister ensure that appropriate epidemiologic surveillance be provided where individuals are known to have been exposed to established or suspect carcinogens?

Answer:	No. A logical answer cannot be given to this question, as posed, unless further defined. To carry this out on all suspected carcinogens would be an enormous cost.
Question 2:	Should employers be required to establish group and individual exposure records suitable for epidemiologic surveillance?
Answer:	Same answer as 1.
Question 3:	Should the minister seek to ensure that appropriate resources are made available to the Ontario Cancer Treatment and Research Foundation in order to guarantee continuance of the Ontario Cancer Registry?
Answer:	Yes. Why not a National Registry?

Issue # 11 — The Provision of Information to the Workforce and to the Public

Question 1:	Should the ministry ensure that members of joint health and safety committees, or members of the workforce where no committees are established, are provided with information, not only on potential hazards but also concerning the chemical structure of any new substance, regardless of whether it is considered by the employer to be safe?
Answer:	Any education should be the responsibility of the company. The government should be prepared to provide this service on request.
Question 2:	Should the ministry establish a procedure to ensure that details of the chemical structure and health effects produced by a new substance are available to the joint health and safety committee (or the workforce), in the event that management fails to provide this information?
Answer:	Only on request.
Question 3:	Should the minister urge the governments of Canada to work with industry, with workers and with the Canadian Centre for Occupational Health and Safety to develop a labelling and colour-coding system which would alert users and members of the workforce to the presence of a carcinogen or suspected carcinogen in any substance to be used?
Answer:	Only where not adequate now.

Question 4: Should the minister make available to the public an index of new substances showing the categories in which they have been placed? Should the data base which has led to this categorization also be made available for public scrutiny?

Answer: Yes.

Question 5: Should the confidentiality provisions of section 34(1)(b) of the Act apply in the case of carcinogens, or should there be full disclosure of all available information to the workforce and to the public?

Answer: There should be full disclosure.

Issue #12 — Penalties for Non-Compliance With the Regulation

Question: Should an employer who introduces a known or suspect carcinogen into the workplace and fails to meet acceptable standards be liable to a penalty in excess of those currently available under section 37(1) of The Occupational Health and Safety Act?

Answer: No.

Issue #13 — Research

Should provision be made for the relaxation of the regulatory requirements in order to permit research in the following areas:—

Question a): research targetted toward the development of new chemicals?

Answer: Yes.

Question b): medical research involving the use of carcinogens for scientific or therapeutic purposes?

Answer: Yes.

October, 1982

J.K. Welgo, P.Eng.
A.G. Cecutti, M.D.

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DR. J. D. LOVERING
MEDICAL DIRECTOR

September 1, 1982

Advisory Council on
Occupational Health &
Occupational Safety
Office of Chairman
400 University Ave.
Toronto, Ontario
M7A 1T7

Attn: Dr. J.F. Mustard

Dear Dr. Mustard:

We have the following comments on the Advisory Council Discussion Paper "The Control of Workplace Carcinogens."

The Special Advisory Committee is to be complimented on producing a generally well-balanced, well-organized, factual report. The report demonstrates that although no occupational cancer "epidemic" exists in Ontario to warrant extreme urgency, some form of control of carcinogens, occupational as well as environmental and lifestyle, is desirable.

However, the Discussion Paper, which concentrates on one class of carcinogens ie workplace carcinogens, is in our opinion less well-balanced and factual, and somewhat contentious. If its purpose was to elicit discussion, I am sure it will be highly successful!

Rather than attempting to present a detailed analysis of the paper and the responses to the Issues questions, we shall make a few general comments, and then some suggestions for your consideration.

1. Justification for Regulation

No defensible justification for introducing regulatory control of workplace carcinogens is presented. Indeed, a reading of the Advisory Committee report would be quite persuasive against regulation, eg an average annual WCB claim load of 16.8 cancer deaths pa over 35 years, would indicate a relatively minor problem compared with other causes of death or disability in the province.

If some form of control (regulatory or otherwise) is found to be desirable, we do not believe carcinogens as a whole should be given special treatment. Carcinogenicity, as well as mutagenicity and teratogenicity, should be regarded as only part of an overall schema for total toxicological evaluation of workplace substances. By singling carcinogens out, other potential hazards of equal or greater significance may tend to be neglected. Evaluation leading to classification done under government auspices implies the setting up of a bureaucracy with its attendant defects.

2. Regulation by Ontario Alone

Ontario would probably lose much more than it would gain if it introduced a system which was different from its main industrial competitors in the other provinces, USA or Europe. The cost, in terms of dollars, lost lead-time, employment opportunities, etc. needs to be thoroughly investigated. It is important for the economic well-being of Ontario that we not be too far out of line with our competitors.

3. Classification

The classification scheme proposed would be highly undesirable. Class I & III chemicals would always be relatively few in number since limited testing facilities are available and cost is high. The vast majority of substances would fall within Class II, the "suspect carcinogen" category. It seems that a substance would be held to be guilty until proven innocent. Thus most substances would have to be treated as suspect carcinogens for many years. This would dilute the objective of controlling exposure to the proven human carcinogens. We note that carcinogens produced during a process as a byproduct would escape the classification system. Also the long-term economic effect on Ontario might be severe if research into and development of new chemicals is unduly suppressed.

4. Definitions

Because current oncology is in a marked state of flux, it is essential that all terms be carefully defined to avoid confusion. The report offers no definitions for carcinogen (human carcinogen per se is not mentioned), suspect carcinogen, chemicals, etc.

5. Format of Report

Section 2 is one scenario of many possible. Section 3 is merely a replay of Section 2 in question format. If a different scenario were presented, many of Section 3 questions would become redundant. Thus specific responses to the issues raised should not be attempted until a more definitive proposal is forthcoming.

We would like to make the following suggestions:

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1. No further action should be taken by the Advisory Council until a socio-economic impact assessment of the necessity for a regulatory approach to workplace carcinogens in Ontario is carried out by an independent consultant.

2. Following issue of the SEIA by the independent consultant:

   a) If a non-regulatory approach is recommended, the best consensus methodology should be developed by an ad hoc committee representing the major Ontario bodies concerned (eg. government, industry associations, major employers, organized labour and professional associations).

   b) If it is established that some regulatory action is needed, the Canadian Association of Administrators of Labour Legislation should be invited to appoint a joint federal-provincial task force to develop a common procedur for hazardous chemicals assessment (including carcinogenicity) in the occupational environment. Affected industries should be allowed to have input via sub-committees set up to explore specific objectives. The consensus produced by such a group may then be adapted to Ontario's specific needs. (This approach is similar to that being taken in the development of an occupational hazard information and labelling standard).

3. The consensus procedure, however produced, should be offered for public review and detailed assessment.

We would be pleased to participate in any meetings or committees which you may organize to assist the Council's further actions.

J.D. Lovering, MD
Medical Director

JDL:tb

Imperial Oil Limited

H. W. SHEA
Corporate Manager, Ontario

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October 21st, 1982

The Honourable R.H. Ramsay,
Minister of Labour,
400 University Avenue,
Toronto, Ontario.
M7A 1T7

Dear Mr. Ramsay:

We welcome the opportunity to comment on both the reference document "Report of the Special Advisory Committee on Carcinogens", and the discussion paper "The Control of Workplace Carcinogens". Rather than presenting extensive and specific comment, we have chosen to set out some essential principles which we feel should be considered in dealing with this matter.

I Report of the Special Advisory Committee on Carcinogens

The report of the Special Advisory Committee on Carcinogens is an excellent technical document. It provides insight into the nature of cancer, cancer deaths in Ontario, the relationship between environmental and lifestyle factors that cause cancer, and proposes methods for evaluating the carcinogenicity of new materials.

It is hoped that future policies directed towards minimizing the incidence of cancer in Ontario will be based upon this balanced rational approach which addresses all the causal factors.

II The Control of Workplace Carcinogens - A Discussion Paper Prepared by The Advisory Council on Occupational Health and Occupational Safety.

1. Regulation of Carcinogens

The discussion paper suggests that the Ministry of Labour be responsible for identifying and regulating the use of carcinogens or potential carcinogens in the workplace. We do not believe that the Report of the Special Advisory Committee presents sufficient justification to warrant a separate regulatory process for occupational carcinogens. The regulation of any substance should be based on all potential health effects and not just on potential carcinogenic effects.

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We believe that, prior to the regulation of any specific carcinogenic agent, the Ministry of Labour should determine that there could be a significant health risk to workers, and that this risk would be reduced or eliminated by regulations. The existing process for establishing designated substance regulations in Ontario satisfies these requirements and should continue to be used in the future.

2. Classification of Carcinogens

The discussion paper also proposes a classification system for carcinogens. It is difficult to provide constructive comment on this classification system as many parameters remain undefined. In principle, we are not opposed to a classification system for carcinogens, provided that it is based on sound scientific principles. Classification of carcinogens at the provincial level, however, can only result in duplication of effort and inefficient use of valuable and limited resources. In our view a national focus for the classification of potentially carcinogenic substances would be preferred, to minimize duplication and encourage national and international cooperation in this activity.

The use of a scientific advisory committee for the evaluation of animal tests and epidemiological data, and for the classification of carcinogens, is appropriate. Such a committee should have a national mandate and be comprised of representatives from appropriate scientific disciplines.

3. Specific Issues

Towards the end of the discussion paper, several issues are presented. Although we have not responded to each issue, we would offer the following comments:

- It is important to separate the classification of carcinogens from regulatory activity. Classification should be based on scientific findings whereas regulation should involve input from government, industry and labour.

- Confidential information must be protected.

- We support the concept of Permissible Exposure Limits in the control of workplace exposure to potential health hazards. Such limits should be based on all potential health risks and not solely on the carcinogenicity of a substance.

As your Ministry is aware, we are prepared at all times to cooperate in initiatives which promote health and safety in the workplace. It is in this spirit that we have offered the above comments and would welcome further consultation on this important matter.

Yours very truly,

HWShea
ds

Inco Limited

Dr. E. Mastromatteo
Director, Occupational Health

November 29th, 1982.

Dr. Fraser Mustard,
Chairman,
Advisory Council on Occupational
Health & Occupational Safety,
400 University Avenue,
Toronto, Ontario M7A 1T7

Dear Dr. Mustard:

Inco Limited welcomes the opportunity to comment on the Discussion Paper "The Control of Workplace Carcinogens" prepared by the Advisory Council on Occupational Health and Occupational Safety.

Before commenting directly on the Discussion Paper, some observations are directed to the very good report prepared by the Special Advisory Committee on Carcinogens. This report provides some excellent background information on the cancer situation in Ontario.

Cancer is not a single disease but rather a complex of diseases with causes related to both environmental and genetic factors. Environmental factors, including lifestyle effects such as smoking, diet, alcohol and sexual activity, are far more significant than those effects directly attributable to occupational factors. This is not to downplay the importance of occupational exposure to carcinogens, but rather to make the point that inordinate attention to one aspect of cancer control will not materially affect the overall burden of cancer in society generally. Control of occupational cancer-causing agents is needed but it should be carried out in the context of all other benefits and risks facing workers and society generally.

The background paper makes clear that the induction of malignant changes in humans from exposure to chemical agents is complex and involves a series of variable events, of which job exposure to a single agent may only be one. The process of cancer induction is further complicated by the interaction of chemical agents encountered both on and off the job which may act as initiators, promoters, antagonists, or cocarcinogens.

The four case histories in the Report of the Special Advisory Committee on Carcinogens point out the lessons which can be learned in cancer control. These lessons include: the prudent application of data derived from experiments in animals to human risks; the concerns about depending on epidemiological evidence of cancer in humans before taking control action; the failure to apply information learned in one country to the experience in other countries; and the "relative failure of public attitude and policy" to do anything about cigarette smoking despite its major importance in the causation of human cancers.

The discussion of cancer statistics from Ontario shows that there is no real age specific increase in cancer incidence in Ontario, except for lung cancer, and this "is attributed mainly to cigarette smoking".

The Special Advisory Committee on Carcinogens also dealt with the screening methods for chemical carcinogens. They noted that "intelligent use of short-term tests offers a faster and less expensive alternative" than tests conducted in animals. The Committee, however, also properly noted that the strengths and weaknesses of these short-term tests "are still not fully appreciated, and practical experience with them is still quite limited". There are other drawbacks to these short-term test systems. For example, they cannot readily evaluate risks associated with processes as opposed to specific agents, particularly when the process involves a mixture of agents, some of which may act as promoters and others as antagonists.

It is with this background that the questions posed in the Discussion Paper about the control of occupational cancer should be reviewed.

The Discussion Paper outlines approaches which could be taken in the identification and classification of substances in the workplace and the control of carcinogenic substances, and raises a number of specific questions. In this submission Inco Limited will respond to the proposed approaches and the questions raised.

At the onset, Inco Limited believes that any approach to occupational health questions should contain, among other things, these two major elements:

1) A review of the available scientific evidence on the risks involved in exposure to stated concentrations of environmental agents encountered in the workplace; and

2) A political/social evaluation of the known scientific evidence.

The first step should involve a credible scientific review by experts in the field of oncology, occupational health, toxicology and related fields. The second step should involve open and public discussion with an opportunity for all those concerned to have input. The regulatory agency has thus to weigh the best available evidence of risk as determined by an independent scientific panel in the light of society's needs in making its recommendations to government. As well as openness, the process should also be flexible to permit changes on the basis of new information or differing perceptions of the needs of society.

Inco Limited offers its views on the issues listed in the Discussion Paper as well as on other issues not listed.

National and International Co-ordination and Co-operation in the Control of Carcinogens

Inco Limited believes there is a need for national and international co-ordination and co-operation in the control of chemical carcinogens encountered in the workplace. It would seem prudent, wherever possible, for the appropriate regulatory agencies to use the provisions in the International Labour Office Convention and Recommendation for the Control of Occupational Cancer. In addition, they should make use of the recommendations of the International Agency for Research on Cancer (IARC) - particularly since Canada is now a member of IARC. IARC has long been involved in the assessment and categorization of chemical substances based on scientific review. IARC has published its assessments in a series of monographs, which are revised as needed. It would not appear appropriate nor necessary to duplicate the work of IARC at either the provincial or federal level in Canada. Where scientific evaluations of specific substances of interest to the province are lacking, or perhaps in question, the province may set up its own scientific review committee or panel. Where the scientific evaluation is of regional or national interest, it would appear better that it be done on a national or international level.

The Canadian Centre for Occupational Health and Safety (CCOHS) has an important role in providing access to published scientific information on chemical substances and to information on the regulatory approaches in other jurisdictions. CCOHS has close links with the ILO data base and likely also with the International Register for Potentially Toxic Chemicals (IRPTC).

An effective international/federal/provincial liaison to co-ordinate information and activity on chemical carcinogens should be established. A particularly close liaison with scientific and regulatory activities in the United States should also be maintained. There is no need to duplicate proper scientific information available in other countries - as is so well pointed out in one of the case studies used by the Advisory Committee in its report.

Advisory Committee(s)

Inco Limited believes that the Minister of Labour should establish scientific advisory committees for the interpretation and assessment of scientific information, and for the appropriate criteria for categorization of chemical substances. The categorization of chemical agents should be based on appropriate scientific review of the activity of specific chemicals. Inco Limited believes that the question of "suitable substitutes" should also be subjected to independent review by appropriate scientists with their recommendations made available to the Minister.

Because of the complex nature of many organic substances and the variation in response between organic and inorganic substances in the short-term in vitro testing, Inco Limited does not believe that a simple schema is appropriate to judge all chemical substances. The scientific advisory committee should be free to determine what scientific criteria will be appropriate for a specific compound under review.

Inco Limited believes that these scientific advisory committees should be set up on an ad hoc basis with specific terms of reference for their tasks. Periodic review should be carried out.

Reporting requirements for New Chemicals

Inco Limited believes that employers should provide disclosure of the available information on toxicity to the Ministry, including the results of tests done to determine carcinogenicity of chemicals introduced into the workplace.

Testing requirements should not be applied to small amounts of new chemicals used in research laboratories or in pilot plants.

In general, the reporting requirements should not be applied to new chemicals which are marketed in Ontario in small amounts, i.e., less than one tonne, unless they are known to be carcinogenic.

Testing Requirements for New Chemicals

Inco Limited does not believe it is feasible to establish regulations on the basis of chemical structure and relationship to known carcinogens. Some polynuclear aromatic compounds are highly potent carcinogens, while others are only weakly carcinogenic or have not been found to have carcinogenic properties.

Inco Limited believes that new chemicals should be subjected to testing requirements as recommended in guidelines. (See below)

Testing Procedures

The testing procedures outlined will require an enormous resource in facilities and personnel for toxicological testing, particularly with the recommendation that all substances in the Environmental Protection Agency (EPA) list used in Ontario be properly categorized "within a period of 5 years". This workload would be increased by the need to carry out tests for reproductive effects and effects on the embryo and foetus as these issues become more important.

The Ministry, with the help of a scientific advisory committee, should publish guidelines on the test procedures which are useful in assessing the potential cancer risk of chemicals to workers. This should aid manufacturers and importers of new chemicals. The United States National Cancer Institute "Guidelines for Carcinogen Bioassay in Small Rodents" are widely accepted for animal bioassay testing procedures. There is, however, no wide acceptance of the appropriate short-term tests and the weighting to give to chemical structure and chemical reactivity. In fact, there is increasing concern about the validity of in vitro tests as predictors of carcinogenicity, particularly for inorganic compounds. The Discussion Paper seems to place more reliability on short-term in vitro tests as regulatory tools than is warranted based on the earlier comments of the Special Advisory Committee on Carcinogens.

In general, the use of guidelines by trained scientists in toxicology, oncology, and occupational health, is preferable to a prescribed and rigid testing procedure. There should be some mechanism for appeal to an independent scientific advisory body by a manufacturer or importer should there be disagreement about the testing required or the category applied.

The document does not touch on cancer induction in animals by routes or techniques that are not considered appropriate to occupational exposure but seems to suggest that animal testing is a straightforward procedure. Inco Limited disagrees with this approach and considers it essential that these questions be addressed in the guidelines.

Testing procedures should be done on the commercial product as marketed or used.

The testing guidelines used by the Ministry should be reviewed periodically - every 3 years seems to be an appropriate time interval for this.

The Classification of New Chemicals

The terms "carcinogens", "suspect carcinogens", "non-carcinogenic", and "confirmed" carcinogens are used in the Discussion Paper. It would be helpful to define these terms for the reader.

In general, Inco Limited supports the concept of categorization of carcinogenic substances into groups, provided appropriate epidemiological and experimental studies as outlined in the guidelines to be produced are followed. Questions about the categorization of a compound should be referred to the scientific advisory committee. Inco Limited would not support the concept of categorization of all chemical substances by a simplistic yet rigid testing system. Professional judgment and discretion on individual substances and exposures, as practised by IARC, would be more acceptable.

The Control of New Chemicals

Inco Limited believes that carcinogenic substances should be regulated.

The American Conference of Governmental Industrial Hygienists (ACGIH) has for many years contained a classification of carcinogens and recommended exposure values to them, as follows:

1a. Human carcinogens with an assigned Threshold Limit Value (TLV)

1b. Human carcinogens without an assigned TLV

2. Suspect carcinogens in humans with control measures "consistent with animal and human experience data".

Inco Limited believes that this approach would be useful in Ontario.

Category II substances should be regulated as "suspect" carcinogens.

Exposure limits should be set for all occupational carcinogens "consistent with the animal and human experience data" as recommended by the ACGIH above.

Ideally, engineering and work practice controls are preferable to the use of personal protective equipment. Personal protective equipment will be needed for some exposures, e.g., exposure to asbestos in demolition work and other jobs which are not strictly maintenance or emergency. Therefore, engineering and work practice controls should not be mandated to the exclusion of other protective measures.

It is not clear what is meant by epidemiological surveillance. Lists of all workers exposed to Category I substances should be maintained as well as information on exposure levels, work history and personal history. It may be too difficult a task to maintain work registers of all workers exposed to all suspect carcinogens as this might represent a very large group of substances from the concepts provided in the Discussion Paper.

Category III substances require no special precautions apart from any inherent general toxicity.

The Testing and Classification of Chemicals Not Considered New

The EPA list contains many thousands of chemical substances. It would require large resources of staff and toxicological resources to study the substances on this list used in Ontario. The Discussion Paper proposes that those used in Ontario for which scientific data are not available should be tested. The EPA list should, however, be reviewed by the scientific committee in the light of information from other jurisdictions. Substances used in relatively large amounts in Ontario and for which there is some index of suspicion should be identified and considered for testing. In general, the manufacturer or importer should pay for the necessary testing where this is required. Where several importers or manufacturers are in the field, the costs should be shared but this may present difficulties.

Government support for testing of priority substances on the EPA list should be considered, particularly for older substances where the original manufacturer(s) is no longer in business but which are now supplied by many small producers or importers.

The Control of Chemicals Not Considered New

Substances which are not considered new and which are subsequently assigned to Category I and Category II on the basis of new information should be subjected to the same requirements as new substances. If used in new plants, the new plant controls should be the same as for a new substance. If used in old plants, the old plants should be given a time period to comply - 5 years or longer would seem appropriate, depending on the nature and size of the operation.

Epidemiologic Surveillance

Inco Limited agrees that epidemiologic and health surveillance should be provided for individuals known to have been exposed to established carcinogens, i.e., Category I substances. The potential list of suspect carcinogens (Category II substances) could well be long and for this reason it would not appear possible to provide the same type of surveillance for all suspect carcinogens, particularly in small industries. A scientific advisory committee may be asked to recommend those priority substances for which exposure and epidemiological surveillance should be recommended.

The Minister should be encouraged to take what measures he could to assist the work not only of the Ontario Cancer Treatment and Research Foundation in its cancer registry work, but also in making more effective use of OHIP, WCB, and the data of the Registrar General for the investigation of occupational influences on disease and mortality.

The Provision of Information to the Workforce and to the Public

Inco Limited believes there should be full disclosure of information on all known and potential adverse effects of a chemical substance. Information on the chemical structure should also be made available provided there is adequate safeguard to protect proprietary information.

Inco Limited believes that the role of the Ministry should be to monitor and audit the programs in place in individual workplaces. Should employers or others fail to meet their responsibilities, then the applicable penalty provisions should apply.

There should be international/national/provincial liaison in the development of labelling and hazard communication for all chemical agents, including those which are carcinogenic.

The question of a colour designation for carcinogens would be difficult. Carcinogenic activity should be noted but only as one property of a substance which may also cause acute narcosis, acute respiratory irritation, pulmonary fibrosis, teratogenic effects, etc. Colour coding for specific health effects would be difficult.

The Ministry should be able to publish a listing of substances reviewed and their assigned categories after they have been considered by the scientific advisory committee and there has been opportunity for input by interested persons.

Inco Limited would not favour the publication of advance lists of "candidate" substances.

The confidentiality provisions of Section 34(1)(b) should not be used to prevent the communication of adequate warnings and directions for proper health and safety precautions. For proprietary products or processes, full disclosure could be made in confidence to the Ministry but such disclosure need not be made to the public.

Penalties for Non-Compliance With The Regulation

Inco Limited is opposed to the concept of tort action for carcinogens or any other substance used in the workplace. The penalty provisions of the Occupational Safety and Health Act should apply to employers. If they are considered currently inadequate, they should be strengthened without the necessity of opening the door to tort action.

Research

Inco Limited believes that the requirements should be relaxed for research and development laboratories and for medical research. The one tonne limitation would also apply here.

General

The questions raised in the Discussion Paper indicate the depth of the Advisory Council's research and their concerns for the control of occupational cancer. Inco Limited shares these concerns.

Ontario standards should not reflect arbitrary classification nor insistence on zero exposure levels for all carcinogens - confirmed or suspect. Each substance should be evaluated individually in terms of its scientific evidence.

Yours sincerely,

Ernst Mastromatteo

E. Mastromatteo, M.D.

EM:P

**Mines
Accident
Prevention
Association
Of Ontario**

**290 Second Ave. W.,
North Bay, Ontario
P1B 3K9**

(705) 472-4140

August 31, 1982

Dr. J.F. Mustard, M.D.
Chairman, Advisory Council on
Occupational Health and Safety
15th Floor
400 University Avenue
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

Please find attached a summary of the comments of the staff of the Mines Accident Prevention Association concerning "The Control of Workplace Carcinogens - A Discussion Paper prepared by: The Advisory Council on Occupational Health and Occupational Safety".

We will be pleased to meet with you at any time to further discuss these comments.

Yours very truly,

E.W. Isaac
Executive Director

EWI/lc

cc: Dr. Ann Robinson

Mines Accident Prevention Association of Ontario

August, 1982

It is appreciated that there is a need for a program to identify and classify chemical substances with a view to controlling carcinogens and suspect carcinogens in the workplace environment. The proposal to establish an advisory committee to assist in establishing such a program is applauded, but it should be emphasized that the structure of such a committee must be such that it have broad representation, with authority to consult with recognized authorities and resources.

The ALARA concept as expressed by the International Commission on Radiological Protection has merit and is based on realistic principles. The concept has been promoted by the MAPAO and accepted in principle by the mining industry for years. This approach has been instrumental in the development and improvement of engineering control in ventilation and dust control in the industry.

It is agreed that appropriate action, including possible financial penalties should follow failure to disclose the use of new substances together with all available pertinent data. However the suggestion that there should be loss of protection from civil liability under the Workmen's Compensation Act is a regressive step which should not be contemplated.

It is agreed that the manufacturers should bear the expense of testing chemicals, but the practicability of such a provision is questioned, since the manufacturer may be out of the country. It is suggested that the manufacturer/importer of a substance currently in use in Ontario bear the expense of testing or obtaining adequate assessment of the potential carcinogenicity of such substances.

We cannot agree with the suggestion that chemicals not considered new should be automatically subjected to test for newly constructed plants. This would be discriminatory and would put an unnecessarily heavy burden on new plants. It would indeed discourage the construction of new plants.

It is difficult to understand the reasoning for suggesting different treatment for substances in Category II, for new plants and existing plants. Surely if it were considered necessary to impose control on substances in new plants, the same must be applied to existing plants without undue delay. There is also a question as to what provisions should be made for the relaxation of regulating requirements for research and other purposes.

ISSUES FOR CONSIDERATION

Issue #1
Co-operation on a national and international basis should definitely be sought. While it will probably be long and difficult it is doubtful if any program will be completely successful without it.

Issue #2
Advisory committee(s) should be established to advise the ministry on all aspects of a regulatory program for carcinogens.

Issue #3
Agreed.

Issue #4
Agreed.

Issue #5
2(d). Testing requirements should be reviewed only if it becomes evident that existing programs need updating or are shown to be inadequate.

Issue #6
Agreed.

Issue #7
(3). The ALARA concept should apply.

(9). Guidelines established to which the ALARA concept applied.

Issue #8
(3). Cost of testing should be borne by the manufacturer or importer.

(4). If the chemical substance is or has been used, the fact that it will be used in a "newly-constructed" workplace does not seem to be the proper reason for performing tests or classification procedures.

Issue #9
(2). Same comment as #8 (4) above.

Issue #10
(2). If the program is as entitled "The Control of Workplace Carcinogens" then items (1) and (3) more than suffice.

Issue #11
Members of Joint Health and Safety Committees should be provided with information on any chemical hazard that is in Category I and information on any chemical used on request.

Issue #12
No, unless such action is wilful and deliberate with complete disregard for the consequences.

Issue #13
No. Research people should be given the same protection as production workers. They are as susceptible to carcinogens as any worker.

Office of Occupational Health and Safety (416) 978-4467

OFFICE OF THE VICE-PRESIDENT — PERSONNEL AND STUDENT AFFAIRS
UNIVERSITY OF TORONTO TORONTO ONTARIO M5S 1A1

November 24, 1982

Dr. J. F. Mustard, M.D.
Chairman,
Advisory Council on Occupational Health
and Occupational Safety,
400 University Ave.,
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

Re: The Control of Workplace Carcinogens

A copy of the discussion paper prepared by the Advisory Council on the control of workplace carcinogens reached me somewhat late in the process, and although no one really speaks for the University of Toronto, I have presumed to express a few of my own opinions which I believe are widely held.

The classification scheme seems unduly restrictive, and we respectfully submit that alternatives are available which would not rely as heavily on in vitro testing. The procedure, unfortunately, appears to reflect the biases of the committee which drafted it. Testing protocols should reflect some practicality, the proposed method appearing to be both unworkable and infeasible.

The proposal seems to ignore much of the information which has been collected by international and other national bodies, such as the International Agency for Research in Cancer, and the National Institute for Occupational Health and Safety in the United States. The risks assessments wherever possible should be based on acceptable data already in place, as well as the cost benefit involved.

We also question the restriction of considerations of this type to carcinogenic materials, and hope that at some time in the future, the Council will generalize its considerations to include all hazardous properties of substances in the workplace, including toxicity, flammability, and explosivity.

Finally, we hope that exceptions will not be made for research institutions to the exposure levels which are acceptable within the research environment. We do not feel that it is practical or feasible for the testing battery proposed to be applied to chemicals which are worked on in chemical synthesis and/or are being synthesized, sometimes for the first time. On the other hand, we feel that it is extremely important that potential exposure to these substances be kept to a minimum. This can be done by assuring and requiring good work practices, adequate ventilation, and training prior to the conduct of research. That is to say that we prefer to set performance standards for the conduct of research which will result in no or minimal exposure rather than engage on a battery of expensive and difficult to interpret tests on substances for which the risks can be minimized by adequate work practices.

I trust the above is helpful to you.

Yours sincerely,

Professor J. W. Smith
Director
Occupational Health and Safety

JWS/rc

Ontario Federation of Labour
Chartered by the Canadian Labour Congress

OFL

15 Gervais Drive, Don Mills M3C 1Y8
Telephone: (416) 441-2731

Clifford G. Pilkey
President

Terry Meagher
Secretary-Treasurer

November 15, 1982

Dr. J. Fraser Mustard,
Chairman,
Advisory Council on Occupational
Health and Safety,
15th Floor,
400 University Avenue,
Toronto, Ontario.
M7A 1T7

Dear Dr. Mustard:

Enclosed is our brief in response to council's Discussion Paper on Workplace Carcinogens.

We are looking forward to addressing some of these issues in the public hearings planned by the council in the new year.

Yours sincerely,

Cliff Pilkey

Clifford G. Pilkey
President

CGP:reb
Encl:
opeiu:343

Ontario Federation of Labour

November, 1982

INTRODUCTION: THE NEED FOR AN OCCUPATIONAL CANCER POLICY

More than four hundred years after miners in the Schneeberg region of Central Europe fell victim to a mysterious disease called "mountain sickness", the uranium miners are still counting the bodies of their brothers who have developed lung cancer as a result of exposure to that same radon gas in the mines of Elliot Lake and Bancroft, Ontario. Studies carried out in Colorado were ignored but even more criminal were the reports developed by the statisticians in the WCB and the Ministry of Labour which were delivered to international scientific conferences, but never released in Elliot Lake. It was the tragedy of Elliot Lake that forced the establishment of the Ham Commission and the passage of the Occupational Health and Safety Act in 1978.

More than two hundred years after Percival Pott described the first known occupational carcinogen, coke oven and gas workers are still counting the bodies of their brothers who were exposed to those same cancer causing agents in Hamilton, Sault Ste Marie and Toronto.

In 1982 in Ontario, we are still debating the relative risks of blue versus brown versus white asbestos, when there is clear human and animal evidence that shows that all asbestos causes cancer.

Despite the fact that every major agency in the US has stated that at the present time it is impossible to estimate human risk from animal studies, and the debate over vinyl chloride in the US produced risk estimations that varied over a million fold,[1] our Ministry of Labour overlooks that hurdle and confidently states:

> "The acceptable annual risk was taken to be 50 excess tumours among 100,000 workers. Based upon the above assumptions the acceptable concentration of vinyl chloride in the air in the workplace was calculated to be 2 ppm."[2]

Not only do we not trust their risk calculation, but the exercise is made even more ludicrous given that the vinyl chloride industry has been operating below 1 ppm for many years. But most importantly, who are these bureacrats and what gives them any right to decide that fifty excess tumours a year is "socially acceptable"?

Even before the debate over the cancer policy, the Ministry of Labour has prejudged the situation and decided that the nuclear industry's approach to "acceptable levels of risk" that gives industry a clear licence to kill is somehow acceptable in Ontario. They gladly adopt this part of the nuclear industry's approach but ignore the ALARA principle (As Low As Reasonably Achievable) which is meant to encourage better controls.

Even before the debate over the cancer policy, the Ministry of Labour has adopted an extremely questionable theory of carcinogenesis. Dr. D. Harding of the Health Studies Service told a meeting of labour and industry representatives convened by the Ministry on July 28, 1982 that they have decided that there are epigenetic carcinogens which induce the chain of events leading to cancer, not by altering the genes but by irritating the cytoplasm in the cell. Such epigenetic carcinogens have thresholds. PCBs are considered by the Ministry to be in this category and Dr. Harding has published a paper arguing that formaldehyde is an epigenetic carcinogen. Labour was told at this meeting, that we have a "bad attitude toward carcinogens"[3] in our wish to eliminate exposures to these substances.

On further investigation, we have found that the epigenetic theory of cancer is being strongly promoted by the Formaldehyde Institute in the U.S. and has been rejected by the EPA Office of Toxic Substances, the National Toxicology Program and the Consumer Product Safety Commission in the U.S. In fact the Office of Toxic Substances concluded in their report:

> *"There is . . . absolutely no scientific evidence for this hypothesis in the published literature."*[4]

Dr. Emanuel Farber, a member of the Advisory Council's Special Advisory Committee on Carcinogens and certainly a world renowned expert in carcinogenesis reviewed Dr. Harding's paper and concluded that it was "Madison Avenue science"!

At the same July 28, 1982 meeting we were told by Dr. Peter Pelmear, the Director of the Occupational Health Branch, that the Ministry has been persuaded by studies produced by Monsanto, who just happens to manufacture PCBS, that they are epigenetic carcinogens and therefore have a "safe" threshold. When asked how he determined the new guideline of 50 ppm, Dr. Pelmear stated that he had called every company that handled PCBS and determined that the exposures ranged from 0.0 to 50 ppm. He then stated that in this case he had used the ALARA principle and set the level at 50 ppm. If the consequences of this bizarre process were not so tragic it would be laughable, but the consequences are borne not by the employers or by these bureaucrats but by working people whose voice is ignored.

There are some 2,820 compounds that are listed in the National Institute of Occupational Safety and Health's 1980 Registry of Toxic Effects of Chemical Substances which have some evidence of tumourgenicity. In 1979 Tomatis at the International Agency for Research on Cancer (IARC) published a list of 111 substances for which there is sufficient evidence of carcinogenicity in animal studies to regard the substances as being carcinogenic in man. A further 100 are suspected because of animal evidence.[5] In November 1982, there are Designated Substance Regulations for only three cancer causing agents in this province.

A survey of workplace exposures carried out by NIOSH in the U.S. found in 4,500 workplaces 70% of the exposures were in the form of trade name products and that in 90% of those cases neither the workers exposed nor the employer had any idea what was in them. When they obtained further information on about half of the 85,000 trade name products, 45% of them contained substances that were regulated by OSHA. When asked how many of those were considered to be trade secrets, they were told at least one third and many of these contained clear carcinogens.[6] Workers are being exposed to cancer causing agents that are hidden by trade names and not even their employers know. There is absolutely no reason to expect that the situation is any different in this province.

There are no mandatory requirements for the pre-testing of workplace chemicals. Workers in this province and this country are still being used as guinea pigs for the profits of industry. In 1982, it is simply a disgrace!

Asbestos workers, miners and smelter workers, auto workers, rubber workers, electrical workers, hydro workers, chemical and oil workers, foundry workers, steel workers, transportation and communications workers, hospital workers, lab workers, textile and clothing workers, food workers, farm workers, dry cleaners, government employees at all levels, wood workers, construction workers, maintenance workers and office workers, to mention only a few are exposed to known and suspected carcinogens every day on their jobs.

The time for a cancer policy is long overdue!

REPORT OF THE SPECIAL ADVISORY COMMITTEE ON CARCINOGENS

1) The Report of the Special Advisory Committee on Carcinogens was a profoundly disappointing document to those of us in the labour movement. It is incredible that a committee set up by an Advisory Council on Occupational Health and Occupational Safety should develop a case study on smoking. The study does not even discuss the potential workplace exposures to side-stream smoke. Nor does it mention that many of the classic epidemiological studies on smoking had no controls for occupational exposures. We certainly do not deny that smoking causes cancer and other health problems, but smoking is a public health problem for the entire population and the Ministry of Labour has no mandate to regulate that.

Perhaps the Committee should be guided by the approaches taken in the U.S., England and Sweden in this respect. Testimony by Richard Lemen of NIOSH before the Royal Commission on Asbestos on July 8, 1981 indicated that NIOSH recommends that people not smoke:

> *"However, we feel in our interpretation of the Occupational Safety and Health Act that we don't have any authority to tell people to smoke or not to smoke, that our authority lies in making recommendations for providing a safe workplace no matter what the personal habits of the individual might be."*[7]

Similarly Dr. E.D. Acheson, who wrote the report for the Simpson Committee in England testified on July 28, 1981:

> *"But I do not consider . . . and again I'm expressing a personal view . . . that the tobacco factor in any way reduces the responsibility of the*

> *asbestos industry to control their standards, to control the dust levels. I think it should be no more dangerous . . . and again I'm expressing a personal view . . . to smoke on the work floor as in the board room, in an asbestos factory.*"[8]

The Swedish delegation stated that prohibition of smoking could not be agreed to by the social partners and Mr. Harold Linton from the Swedish Ministry of Labour stated:

> "*Smoking is a general health problem for the entire population, and it is mainly a question for the Minister of Social Affairs, and she has been trying to put forward a bill which should ban smoking in all official buildings. But she hasn't succeeded.*"[9]

If the Ministry of Health in this province wishes to issue regulations controlling people's lifestyle then so be it. But we are sure that they will have difficulty persuading the Ministry of Revenue who took in $345 million in cigarette taxes between April 1, 1981 and March 31, 1982. Not to mention the federal income raised by the 3¢ on every five cigarettes in excise tax or the 12% sales tax.

While the Committee points out that 80% of the lung cancer in males and 60% in females is attributable to smoking they do not point out that the rate of lung cancer deaths in non-smokers approximately doubled in the U.S. between 1958 and 1969 and has maintained that increase ever since.[10]

They conclude that any increase in lung cancer is mainly accounted for by smoking and that any regional differences, which show higher rates of lung cancer in heavily industrialized areas can be mainly explained by differences in smoking habits. There are no references on which they base this statement. A report from Doll and Peto's institution in England, however, demonstrates that the correlation coefficient between lung cancer and smoking internationally explains only one third as much of the variation as does the correlation coefficient between lung cancer and solid fuel consumption.[11]

There is no breakdown as to what kinds of lung cancer occur. Many of the occupational lung cancers are different from the small-cell undifferentiated and squamous cell cancers due to smoking, but the statistics do not indicate how many die from adenocarcinoma which characterizes many workplace exposures.[12]

The Committee's seeming obsession with smoking will be used by industry to attempt to deflect attention from the very real opportunity we have to reduce and eliminate exposures to the cancer causing agents in our workplaces and to prevent the introduction of any new ones. They state that the removal of asbestos alone could eliminate 90% of the cancer among that high risk population and that smoking would eliminate 79% of the cancer. So let us deal with the exposure we can control.

It is time to heed the warning of the Surgeon-General in the U.S. whose 1979 Report on Smoking and Health stated that the over-emphasis on smoking has diverted attention from other important causes of lung cancer.[13]

2) The Committee's conclusion that:

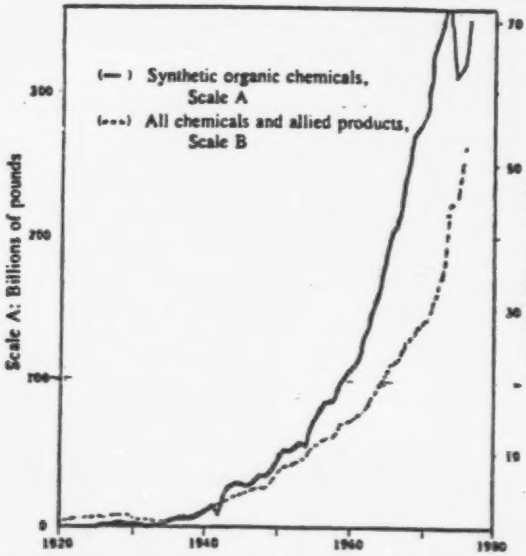
> *"There is no convincing evidence that there has been at least up to the present time, any significant increase in cancer in the population as a whole due to chemicals introduced in the last 15 to 25 years."*

is equally disappointing. They do admit that perhaps the latency period has not been long enough and that provincial statistics may be too crude to pick up the increase but we have already seen this conclusion used to argue against the need for a cancer policy.

As the graph below indicates, the use of synthetic, organic chemicals and all chemicals grew exponentially from the mid 1960s on. It is impossible to draw any conclusions about the cancer impact of these chemicals in 1982.

Figure 1

Total Synthetic Organic Chemicals, Annual Production (excludes tar, tar crudes, and primary products from petroleum and natural gas) Total Chemicals and Allied Products, Annual Value Added[14]



3) Despite the Committee's warning that WCB statistics underestimate the true incidence of workplace cancer, industry has already used the annual case load of 16.8 claims to trivialize the problem and the need for regulation. Peter Barth, who carried out a study on compensation for the Royal Commission on Asbestos looked at the problem of underreporting of asbestos cancer. Using mesothelioma as the marker disease he estimated how many other cancer cases would be expected. Only 44% of the total lung cancer claims expected were submitted to the Board and only 40% received compensation.[15] And that is for a work-related disease that is probably better known than any other.

The labour movement in this province believes that the estimation that 20 to 38% of all cancer is attributable to workplace exposures is not only fair but probably underestimates the amount.[16] Workers in this province are exposed to far more than the six carcinogens studied, not the least of which is radiation. And furthermore, many of these exposures have been largely uncontrolled. For example, as late as 1974 miners in the Reeves asbestos mine were exposed to levels of 30 to 200 times the allowable limit according to Johns-Manville's own hygienist.

The NCI, NIEHS and NIOSH estimations were based on the risk effect to the exposed populations and were not diluted by the general population. If you take the conservative estimate of 20%, more than 2,834 workers died in Ontario in 1979 of cancer. If that is not an epidemic we do not know what is!

4) At least two other lessons should be learned from the vinyl chloride case study. In fact animal screening did detect the carcinogenic effects of vinyl chloride before human data was available, but the Manufacturing Chemists Association chose not to publish Viola's 1971 findings. Even Maltoni's 1972 results which confirmed and expanded the earlier study were not made public until 1974, when B.F. Gooderich announced that three of their Louisville, Kentucky workers had died of angiosarcoma. The National Association for the Advancement of Science concluded:

> *"Because of the suppression of these data, tens of thousands of workers were exposed without warning, for perhaps two years, to toxic concentrations of vinyl chloride."*[17]

If this was a single incident of aberrant corporate behaviour it could be ignored but the same lesson is learned again and again in asbestos, DBCP and benzene to mention only a few.[18] The lesson that labour takes from this example is that there is a clear need for independent testing by reputable scientists and paid by industry.

As well, the vinyl chloride case study teaches that the industry to be regulated is not the appropriate institution to be calculating the costs of such regulation. The vinyl chloride industry deliberately overestimated the costs when it reported that the 1 ppm standard would cost $92 billion and 2.2 million jobs lost. In fact the initial capital cost was $34 million with savings earned and no jobs lost.[19]

5) And finally we are concerned about the suggestion made by the Committee that an example of a radiation control program might be found in the nuclear industry in Ontario. Despite the criticisms that are raised about risk assessment in the case study this suggestion seems to endorse the concept of "acceptable levels of risk". Is it acceptable that we have already seen two men who have paid the price for those "acceptable levels" and that both Hydro and the AECL predict more victims? Is it acceptable that more than 100 miners have developed lung cancer from working in the uranium mines for our nuclear industry? Perhaps those who make the decisions would like to explain to their widows and children how they determined that the deaths are somehow "acceptable". We, in the labour movement, who do see the widows and children cannot.

THE CONTROL OF WORKPLACE CARCINOGENS

Unlike the *Report of the Special Advisory Committee on Carcinogens* the discussion paper entitled *The Control of Workplace Carcinogens* attempts to focus entirely on workplace carcinogens and the Council should be congratulated.

Limited Scope of the Policy

As we have stated in our Introduction there is a clear need for a cancer policy in this province if not in this country, but of equal concern is the growing knowledge that workplace chemicals also cause reproductive problems and birth defects. A tragedy for the next generation, if indeed there is one.

J. Donald Millar of NIOSH has stated that there are 1,800 substances in the Toxic Substance Registry for which one human or one animal study has shown teratogenic or other reproductive effects. It has been estimated that 20 million jobs in the U.S. carry the potential for adverse reproductive outcomes.[20]

These chemicals must also be tested and classified according to their potential teratogenic or mutagenic effects and efforts must be made to remove the substance from the workplace. The current practice of removing women of child bearing years unless they can show sterility is totally unacceptable from a human rights point of view. Not only does it discriminate against the women involved, but it leaves the men in potentially hazardous exposures for their reproductive lives as well.

While we recognize that this discussion is focused on cancer and we will limit our remarks to the testing and classification of carcinogens, we appeal to the Advisory Council and the Ministry of Labour not to ignore this problem until the next generation asks why.

The discussion paper focuses entirely on chemicals. The recent controversy over video display terminals surely indicates the need to expand testing requirements to any possible cause of cancer in the workplace, especially before it enters the plant. As well, by-products are important sources of workers' exposures and processes must be tested for potential carcinogenic effects. The foundry study at Dofasco shows clearly that it is not always possible to isolate the individual component or components which cause the excess lung cancer.[21]

The discussion paper emphasizes the testing and classification of new chemicals and certainly the new chemicals provide us with an opportunity to stop carcinogens before they enter the workplace and multi-billion dollar industries are based on their use. But there are some 55,103 chemicals used in workplaces now and most of them have not been tested.[22] We therefore, heartily endorse the discussion paper's recommendation that these chemicals must be properly categorized within five years.

And finally, we agree that for a single province to undertake such a project is overwhelming. The federal government must be encouraged to undertake such a testing and classification project through the Canadian Centre for Occupational Health and Safety. Industry will argue that limiting exposures to cancer causing agents in one province will create an unfair competitive disadvantage to Ontario industry. We would argue that to deprive all Canadian workers of stringent protections against carcinogens raises significant questions of equity and fairness.

ISSUES FOR CONSIDERATION

In responding to these issues the labour movement wishes to make clear that we endorse a very basic assumption which must apply in considering the use and testing of all chemicals or physical agents. We believe that all chemicals or physical agents must be considered guilty until proven innocent. We place a high value on civil liberties in the judicial system, where we generally believe that the aquittal of the guilty is less harmful than the conviction of the innocent. But in the case of toxic substances, this idea of innocent until proven guilty makes no sense at all. Granting civil rights to chemicals may very well deny them to human beings. Presuming chemicals innocent until proven guilty makes people the victims unless they can sustain enormously difficult burdens of proof.[23]

Issue #1

1) Federal co-operation and co-ordination is absolutely essential but if such action is not forthcoming, Ontario must proceed on its own. As one of the most industrialized provinces we have a responsibility to set an example and to protect the workers under our jurisdiction, at least.

2) The use of international data is also essential given the enormity of the task and the waste of resources in reproducing similar tests. However, our experience with Industrial Bio-Test Laboratories in the U.S. where fraudulent results were developed for regulatory agencies in the U.S. and here in Canada, would encourage the careful scrutiny of just who is carrying out the tests in those jurisdictions.[24]

3) The International Labour Organization is subject to even greater tradeoffs than most agencies responsible for developing recommendations, therefore, we do not think that these should form the basis of our standards. They are clearly a minimum. At the same time it is shocking that we do not even subscribe to such a minimum. No Ontario standard has encouraged the substitution of less hazardous chemicals and the vinyl chloride standard is certainly not complying with Article 2 of the ILO Occupational Cancer Convention, 1974.

Many countries have excellent programs for testing and classification: The IARC in France, the EPA's Office of Toxic Chemicals, The U.S. National Toxicology Program, the Toxic Substance Control Act program and the Interagency Testing Committee in the U.S., and the efforts by the European Economic Community should also be monitored.

Issue #2

A permanent committee should be established with full-time paid representatives of labour and management. The majority on the committee would represent workers since they are the ones who must assume any risks from the decisions involved. The committee would have an technical staff who can advise and they would decide on the need for more testing or information. Since we reject the possibility of introducing new carcinogens into our workplaces, this committee would decide on any exemptions to this rule.

Industries who use known or suspected carcinogens would have to justify their continued use to this committee and present plans for the elimination of all workplace exposure and the eventual substitution of less hazardous chemicals.

Since we also reject the exemption for those industries producing less than one tonne, as recommended in this discussion paper, the committee would hear appeals for the use of carcinogens for research or development purposes.

Where "old" chemicals are identified as being known or suspected carcinogens, the committee will direct the Ministry of Labour to send a cancer warning to the joint health and safety committee or a worker representative in every workplace where there might be an exposure. Such warnings will also be broadly publicized in the media.

Where "old" chemicals are identified as being known or suspected carcinogens the committee will direct the government to issue an emergency standard within 60 days.

Issue #3

1) The Minister must develop reporting requirements for the full disclosure of all chemicals before they are introduced into the workplace, describing their chemical formulation, any testing carried out to date, the intended use of these chemicals and the potential interactions with other chemicals to produce by-products.

As well the Minister should require reporting of all chemicals used at this time, with chemical formulations, any test results, a description of the use of these substances, their interactions with other chemicals, by-products produced in the process, exposure results and the numbers of workers potentially exposed. This information should be approved by the joint health and safety committee or a worker representative where there is no committee.

Such information on "old" chemicals can be used to prioritize the further testing and regulation. The Ministry of Labour attempted to get some of this information voluntarily with little success so that it is necessary to legislate the requirement. As well, the approval of the joint committee or a worker representative with a posting of the list would do much to fulfill the workers' rights to know about all the hazards on their jobs.

While this paper addresses carcinogens only, the Ministry must be interested in other health effects as well, for the purposes of testing and regulation.

2) No blanket exemptions from the reporting rule. Exemptions can be made by the committee for purposes of research and development, as long as they are satisfied that every precaution is taken to eliminate worker exposure, that every worker involved is fully informed of the possible hazard and that they have the right to refuse without penalty.

Issue #4

1) All new chemicals should be tested. Their chemical structure and relationship to a known carcinogen would certainly prioritize their testing but no chemical should be allowed into the workplace until it is thoroughly tested.

2) The testing must be carried out by an independent approved testing facility or accepted by an approved International Agency. The manufacturer or importer has the financial responsibility for the tests and must provide the results to the government. They may not introduce the chemical until it is approved by the committee and then the government.

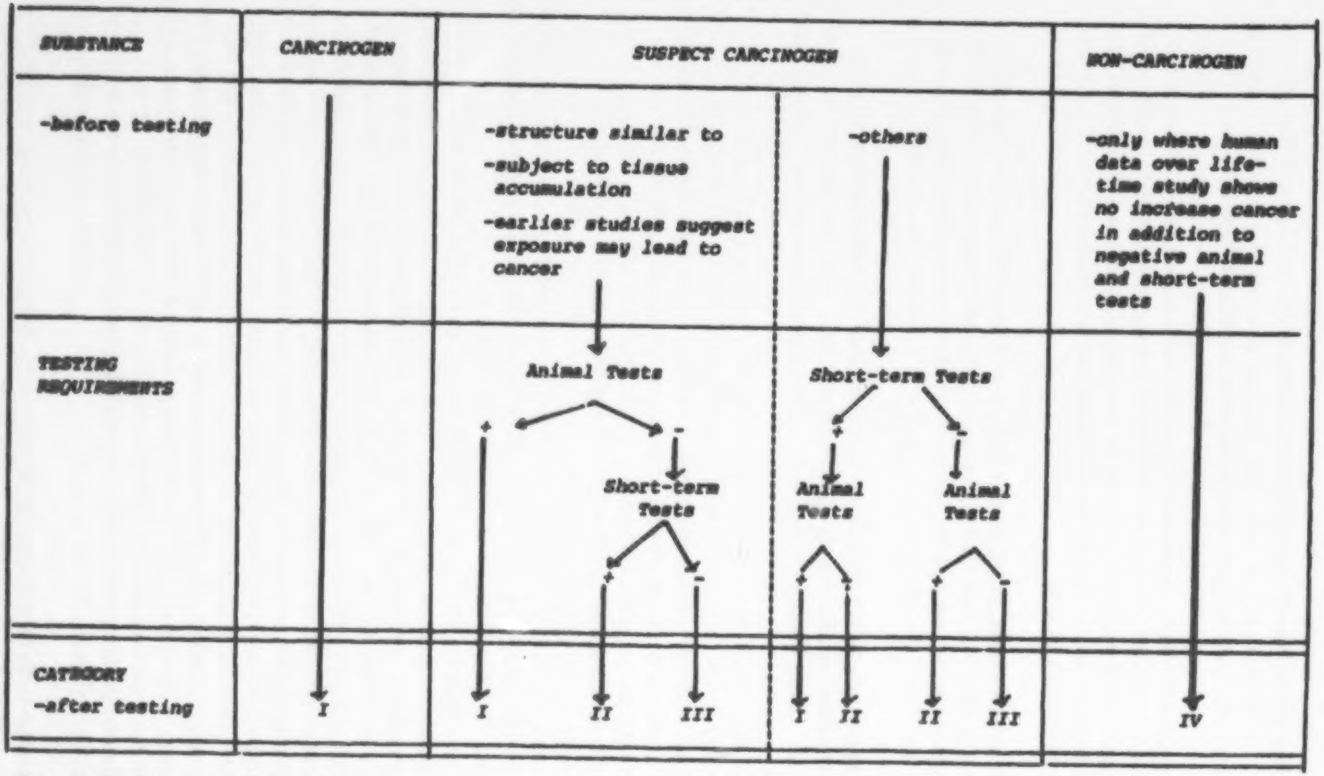
When a chemical is assessed to be similar or related to a known carcinogen, we agree that it should go on to long term animal tests. The problem that we have is that negative animal tests might end up as Category III (Non-carcinogens). The problem of false negatives in animal testing is of very real concern to those who must bear the risk of the possibility of being wrong. Arsenic is a perfect example, and there is some argument about benzene. Both are clear human carcinogens.

We think that another category should be added. The new Category III would be chemicals for which animal and short-term testing has been negative. In this case the potential carcinogenicity is still unknown. Exposures to these chemicals should be controlled to as low as possible and the workers should be followed up to detect any possibility of cancer.

The new Category IV (Non-Carcinogens) would include only those who have negative animal tests, negative short-term tests and negative human data from a well constructed epidemiological study that has followed the workers for at least thirty years and preferably for a lifetime. These chemicals would be regulated for any other health effect that is shown.

The Classification system we recommend follows on the next page.

CLASSIFICATION OF SUBSTANCES IN THE WORKPLACE


SUBSTANCE
CARCINOGEN
SUSPECT CARCINOGEN
NON-CARCINOGEN
-before testing
-structure similar to
-subject to tissue accumulation
-earlier studies suggest exposure may lead to cancer
-others
-only where human data over lifetime study shows no increase cancer in addition to negative animal and short-term tests
TESTING REQUIREMENTS
Animal Tests
+
-
Short-term Tests
+
-
Short-term Tests
+
-
Animal Tests
Animal Tests
+
-
+
-
CATEGORY
-after testing
I
I
II
III
I
II
II
III
IV

KEY: CATEGORY I - CARCINOGEN
CATEGORY II - SUSPECT CARCINOGEN
CATEGORY III - UNKNOWN
CATEGORY IV - NON-CARCINOGEN

Where there are negative animal tests and short-term tests the Committee can decide if additional testing is required.

Issue #5

1) The permanent committee would recommend to the Ministry the testing protocol required.

2) Yes, the *"Guidelines for Carcinogen Bioassay in Small Rodents"* produced by the National Cancer Institute in the U.S. should be followed.

3) Yes a minimum of two short-term tests should be required.

4) This is a difficult question and one that would depend on the nature of the exposure and the chemical. Ideally the tests should be carried out on both commercial and purified samples. Of concern to labour is also the potential interactions of substances in the workplace which produce another or even more potent carcinogen.

Workplace environments are not duplicated in the lab. Animals are tested with only one chemical and are kept at a constant temperature, whereas the workplace can be a veritable sea of toxic chemicals and the temperature may well alter their structure.

5) Any advancement should be monitored and decisions made when new test protocols are developed. The three year rule must not prevent the use of better testing technology when it is developed and approved by the committee.

Issue #6

Positive results must supersede negative results. Because of the insensitivity of animal tests to predict the response in a human population any positive animal results must be considered very important. As well because of the insensitivity of epidemiological studies positive animal results must supersede negative human results.

At the OSHA Hearings over the U.S. Cancer policy, Dr. Arthur Upton, Director fo the National Cancer Institute stated:

> *"Given this lack of knowledge concerning mechanisms, I believe that a reproducible carcinogenic response in* any *species of test animal must be considered sufficient to describe the test compound as a carcinogen and so a potential threat to human health. I consider that a similar reaction in a second mammalian species is a confirmation of the carcinogenicity of the test agent, but it is not necessary before a finding of carcinogenicity and potential threat to human health can be made: negative results in a second or even third species of test animal do not in my mind establish that the test agent is not a potential threat for human beings. Given the variation in human susceptibility to carcinogens, I believe it unreasonable to ignore a finding of carcinogenicity in any mammalian test species when considering possible effects on human health."* (Upton. S. 17)

Dr. Umberto Saffiotti, also of the NCI:

> *"Conclusive evidence of carcinogenicity in one species supersedes negative findings in other species in the extrapolation of risk to man, since no basis presently exists to rule out the likelihood that human beings*

respond in the same manner as the positive test species." (Saffiotti, S. 34)

And Dr. Robert Hoover of the NCI:

> "*Because of the severe limitations of each of these methods of investigation, a good study showing positive evidence of carcinogenicity should take precedence over negative studies. For example, animal studies are hindered by the inability to routinely evaluate the effect of low-level exposures, and the potential problems of species specificity. On the other hand, human studies are hindered by the inability to identify low-level, but substantial, increases in risk, the long latent period between exposure and disease, and the influences of multiple exposures and differing host susceptibilities.*" (Hoover, S. 20)

Negative epidemiological results cannot override positive animal results because of the very real methodological problems in epidemiology and the insensitivity of these studies to demonstrate positive results in anything but very potent human carcinogens.

Dr. Richard Bates of the National Institute of Environmental Health and Safety and the Federal Food and Drug Administration told the OSHA Cancer Hearings:

> "*Few epidemiological studies of occupational cancer have been of adequate sensitivity to detect anything smaller than a 50% increase in the incidence of cancer over that found in the general population. Weakly carcinogenic agents, that is those capable of inducing cancer only in the most highly susceptible individuals at the level to which the worker population is exposed, would not be detected by most studies.*" (Bates, S.7)

Most epidemiological studies suffer from inadequate exposure data, according to Dr. David Wegman of Harvard University:

> "*. . . I have yet to see and would be surprised to see adequate, historically collected exposure data to provide us with sufficient evaluation of exposure retrospectively; that is, looking back in time to exposures that have already occurred, to predict that we could come up with, starting today on old data, a negative epidemiologic study that could rule out an association between a given exposure and a risk of cancer that is related to that exposure, because the exposure data is not there.*" (Wegman, Tr. 1681-1682)

All of these quotes can be found in the *Federal Register*, referenced in the footnotes.

And two respected scientists testified that they had never seen a good negative epidemiological study:

> "*I do not know of any good epidemiological negative study where a compound is a proven carcinogen in animals, where you have a good or acceptable study in humans and where you can say, 'This study does not show cancer in people and it has been proven beyond a doubt*

> *that it does not show cancer in people. I just cannot think of one.*" (Renate Kimborough, CDC, Tr. 1791)

and

> "*I have never seen a good negative study. I mean I am an epidemiologist. I know most of the cancer epidemiology that is done and the negative studies that are done are not — I mean, I cannot think of any case where it is clearly proof that the substance is safe. It is very difficult to distinguish between exposed and unexposed and to find people who are exposed for a long time.*" (Richard Peto, Tr. 2547)

Given these respected opinions we therefore propose the following classification system.

CATEGORY I	Positive, significant results in any of the following: – one epidemiological study – two animal species – one animal species duplicated in a second study – one animal study supported by positive results in short-term studies. – one animal study where there is overwhelming evidence ie. high incidence of tumours or the occurrence of rare tumours. – where other evidence is considered appropriate by the committee.
CATEGORY II	SUSPECT CARCINOGENS – where there are conflicting animal results – where there are positive short term tests but negative animal tests in at least two species.
CATEGORY III	UNKNOWN – where there are negative short-term tests and negative animal tests in at least two species.
CATEGORY IV	NON-CARCINOGENS – where there are negative short-term tests and negative animal tests in at least two species and there is a negative result in a carefully constructed epidemiological study which has sufficient exposure data and at least thirty years if not life-time follow-up.

Issue #7: The Control of New Chemicals

1) No new chemical that is classified as a Category I Carcinogen will be allowed into any workplace. The Committee can grant exemptions to this rule but the only exemption that can be foreseen is the development of new chemicals for medical therapy.

We do not need any more carcinogens in our workplaces or the environment, and the pre-testing of these chemicals provide the chance to stop their introduction before entire industries are dependent upon them. The ILO principle of substitution of safe alternatives must apply from the beginning.

3) Where the committee has allowed an exemption, there should be no detectable exposure, the workers must be fully informed that the substance is a carcinogen, and that they have the right to refuse to handle the substance without penalty.

4) Category II substances must be treated as Suspect Carcinogens and the Committee must decide on an individual basis which substances will be allowed into any workplace.

5) Category II substances will be treated as carcinogens in the sense that there should be no detectable level, the workers must be fully informed that the substance is a suspected carcinogen, and they have the right to refuse to handle the substance without penalty. Where the substance is allowed the workers must be followed up to detect any possibility of cancer.

6) In general Category I new chemicals will not be allowed into any workplace. But where Category I or II are allowed the no detectable levels will be met through engineering and workplace controls only.

7) Personal protective equipment can be used only for maintenance and emergency purposes and must ensure no detectable exposure during that time. If workers wish to wear protective equipment as an additional precaution, the employer must supply it.

8) Epidemiological surveillance should be maintained for workers exposed to Category I and II where allowed, and for those exposed to Category III and IV. The inevitability of being wrong in these last two categories make it important to follow the populations.

Issue #8: Testing and Classification of ''Old'' Chemicals

1) Having received the lists of chemicals in use and the numbers of workers exposed from the mandatory notification requirement described before, the Ministry can prioritize the chemicals by assessing how much is used and how many are exposed, what is known to date, how other approved agencies have categorized them, and whether they resemble any known carcinogen.

2) Where testing is considered necessary, independent approved laboratories should carry out the tests paid by the manufacturer or the user if the substance is imported and not properly tested to date.

3) If the chemical has already been tested and classified and subjected to whatever regulation is necessary, its use in a newly-constructed workplace should not be considered a new chemical. If the substance is a Category I Carcinogen permission to use the chemical until a safe substitute is found must be granted by the committee. If the substance is going to be used in an entirely new way, it should be subject to the new chemical test requirements.

4) The classification should take place as quickly as possible and within no longer than five years.

Issue #9: The Control of "Old" Chemicals

1) a. The use of a Category I Carcinogen in a new plant must be approved by the committee and subject to the same stringent regulations.

1) b. Any employer using a Category I Carcinogen must justify its continued use to the committee where no safe substitute is available. Immediate notification to the workers, regulations limiting exposures to no detectable levels, and the other requirements described for Category I substances will apply within 60 days.

2) a. Category II Suspect Carcinogens must be approved for use in a new plant by the committee and subject to stringent regulations limiting exposure to no detectable level etc.

2) b. In an existing plant immediate notification to the workers, and regulations limiting exposure to no detectable levels will also apply.

3) All users of chemicals will be required to meet the stringent requirements of new chemicals within the time set in the regulation.

Issue #10: Epidemiologic Surveillance

1) All workers should be followed to identify any breakdown in the classification or regulatory system. Employers should pay a % of wages to a fund that will be used for such research.

2) Accurate exposure records are absolutely necessary for a good epidemiological study.

3) Attempts should be made to get better occupational information on any cancer victim.

Issue #11: Workers' Right To Know

1) There should be a mandatory requirement that the employer provide to the joint committee or the worker representative and post for all workers to see, the list of all chemicals and physical agents used in the workplace, with the potential hazards, the chemical formulation, the amount used, the use to which it is put in the process and the potential jobs exposed. This information is required to go to the government for setting priorities in testing. Any new chemical must be added to this list.

2) Since the government will have this list, they must ensure that the employer complies and where he or she refuses, charges should be laid and a copy of the government's list should be given to a worker member on the committee or a worker representative for posting.

3) Labelling of all chemicals or physical agents is important but especially carcinogens. Clearly a national labelling system would be of great benefit and we would be satisfied to see the Canadian Centre undertake such a project. A cautionary note should be added about colour coding information. Shapes are considered to be a better informer given the incidence of colour-

blindness. As well, written labels presume knowledge of the language used and literacy.

Where any known or suspected carcinogen is allowed to be used, notices must be placed at the entrance and on the walls warning workers of their presence.

4) All of the classification data must be available for public scrutiny. The lists must be updated regularly and made available to libraries, labour unions, manufacturers' associations and to the media. Notification of any Category I or II Carcinogen must be sent to any user and the health and safety committee or worker representative and placed in the media.

5) Workers have a right in natural justice to know what they are working with: they are not interested in selling trade secrets. Section 34 (1)(b) essentially prevents worker committee members from sharing essential information with their brothers and sisters in the workplace. It is unacceptable. Consideration should be given to the public's right to know what a neighbourhood industry may be introducing into the environment.

Issue #12

The courts find it very difficult to act in a preventative way when there is no victim. Even where there is a victim the fines range between $1,000 and ten thousand dollars for the death of a female Inco worker. Hardly an incentive to take health and safety seriously. The Attorney-General must instruct the prosecutors to demand the maximum penalties including jail terms.

We consider the introduction of carcinogens without notification a serious offence, but we are not prepared to say that it is more serious than an employer refusing to screen a dangerous vat. Any failure to comply with the regulations is a serious offence and the penalties for any form of negligence must be increased. A death from cancer should not be judged as more significant than a municipal worker drowning in a storm sewer or a miner dying in a rock fall. All of these workplace deaths are completely preventable and the penalties should reflect a desire to value all human life.

CONCLUSION

Although it was not raised as an issue in the discussion paper, we must raise our objections to the increasing practice of genetic screening for cancer-prone individuals and the discriminatory practice of excluding hypersensitive workers. Such action, like fertility screening is discriminatory on the two counts mentioned before. It not only discriminates against those who are found to be genetically "inferior", a concept reminiscent of Hitler, but leaves the "super-workers" exposed to the carcinogens. The problem is the chemical or the physical agent and the solution is to rid our workplaces of known and suspected cancer causing agents.

We reject the entire concept of "acceptable risk" and the calculations inherent in the process of risk assessment that leads to this decision. Animal and short-term testing can identify carcinogens qualitatively. However, the next step is to quantify risk and this is impossible at the present time.

Methods for quantitative risk assessment require a number of choices and assumptions to compute the risks at low levels of exposure: the choice of data set(s), choice of mathematical model, correction for lifespan differences in animals and man, calculations of dose, variability in multiple exposures, state of health and genetic background that occur in humans and not in test animals. All of these choices are subjective and introduce considerable uncertainty. In fact, the risk estimations produced for vinyl chloride varied by a magnitude of more than a million fold, and the estimations for saccharine varied by a factor of 10 million fold.[25]

There was much evidence offered by experts confirming the inability to quantify human risks from animal studies at the Cancer hearings in the U.S., and an important warning was released from the National Cancer Institute to the U.S. Food and Drug Administration in 1979. They stated that the FDA should not abandon the rigid Delaney principle which prohibits carcinogenic additives for a more flexible risk benefit approach:

> *"Conclusion — Although an attractive idea, quantitative risk assessment involving extrapolations from animal data is not yet sufficiently developed to be used as a primary basis for regulating human exposure to carcinogens. Although we are correct in concluding qualitatively that animal carcinogens are potential human carcinogens, quantitative extrapolations involve potentially large errors, some of which could underestimate the actual human risk from exposure. Scientific knowledge is currently insufficient to lend precision to this process."*[26]

Epidemiological studies also suffer from enormous methodolical problems and subjective choices and assumptions. Small numbers, insufficient latent periods, incomplete follow-up, multiple exposures, and insufficient exposure data characterize most epidemiological studies. According to Dr. Selikoff, quantitative risk assessment is not even possible for asbestos — the best studied occupational carcinogen for which follow-up has been extensive and exposure data has been determined. Certainly the evidence given during the expert testimony at the Royal Commission on Asbestos in this province would confirm Dr. Selikoff's conclusion:

> *"Human data are not sufficiently valid to define a dose-response relationship at low concentrations for a meaningful numeric data standard setting."* Selikoff, Transcript 1731-4)

To then use these extremely questionable risk estimations to balance off risks and benefits or to carry out cost-benefit analysis is even more unacceptable. In an article written for a conference on risk management for carcinogens, Dr. Nicholas Ashford summarized the flaws inherent in cost-benefit analysis:

- *There are important differences between economic regulation and environmental, health, or safety regulation that must not be overlooked.*
- *Costs are easier to express than benefits, but their quantifiability makes them no more certain or reliable.*
- *Benefits include improved quality of life and good health as well as positive economic side-effects, but they defy accurate estimation and their recipients are not a well-organized lobbying group.*

- *The comparison of costs and benefits is beset by serious methodological difficulties and requires the analyst to make value-laden assumptions; yet cost-benefit analysis appears, deceptively, to be a neutral technique.*
- *Insistence on cost-benefit decision rules and other regulatory "reform" efforts may be undemocratic attempts to reorient legislative mandates.*[27]

OSHA in the U.S. faced these problems in the deliberation over their cancer policy and concluded:

> *First, the state-of-the-art of quantitative risk assessment techniques particularly for carcinogens, that are crucial to cost-benefit analysis, is too crude and unreliable to permit the refined estimates necessary to determine risk reduction at various exposure levels.* OSHA *believes that estimates with such wide variations that may understate cancer risks by orders of magnitude are not useful in setting control levels. Cancer is an irreversible disease leading to death with no demonstrated threshold or safe level, and thus requires a highly protective regulatory approach.*
>
> *Secondly, as a matter of policy, efficiency criteria alone are not appropriate because they ignore equity considerations. The economic savings from less protective regulation accrue to industry in the form of higher profits and consumers in the form of lower prices. But the costs are borne by workers through increased industrial illness and death rates.* OSHA *believes that it would be inappropriate for an agency statutorily required "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions" to ignore such equity considerations.*[28]

By refusing to allow new carcinogens into the workplace and limiting exposures to a no detectable level for those already present until the substitution of "safe" tested alternatives is possible, we are recommending a prudent public health policy. Additional research is not necessary for us to move immediately to protect workers against cancer.

Many will argue that now is not the time to regulate, that we should be concerned about productivity and inflation. Well just as workers' wages have been incorrectly diagnosed as the cause of inflation so too is health and safety regulation. In a study prepared for the President's Council on Environmental Quality in the U.S., the annual inflationary impact of pollution regulation on the consumer price index was 0.2%[29] The Council on Wage and Price Stability in the U.S. estimated that all regulation contributed 0.75% to the annual inflation rate and more than half of that was due to cartel regulations.[30] The charge that health and safety regulation, whether for workers or the public, is the cause of inflation may have a nice polemic if not poetic ring to it, but it has no basis in fact. The cause of our double digit inflation lies elsewhere.[31]

While we have heard accusations of low productivity from Canadian workers, we have not heard about the 18.9 million man days lost to production as a result of occupational injury, illness and death in 1979. And that figure is based only on compensation claims accepted, a figure that is known to grossly underestimate the true incidence. On the other hand, we certainly *did* hear a lot about the 7.7 million man days lost to production in that same year due to strikes and lock-outs.[31]

If one looked at the more than one billion dollars paid out in direct compensation to the victims of our failure to regulate and enforce, or the estimated \$4.3 billion in indirect costs,[32] we might gain a small sense of the economic impact of our past failures. While these figures represent the impact of accidents and other toxic exposures the cost of almost 3,000 victims of workplace exposures to known carcinogens every year is clearly unacceptable to any society. Now, indeed is the time to regulate the pretesting of new chemicals and the strict regulation of those carcinogens in use, until they can be substituted with "safe" alternatives. To do less is to sentence our economic recovery to increasing lost production and spiralling health costs.

But over-riding any of these arguments is the basic premise on which every civilized society is based "Thou shalt not kill!" While it may be expressed differently in every organized religion and in the laws of every country, the value of human life remains the same; and it is not open to the proposition that it is all right to kill if *not killing* is too expensive.[33]

FOOTNOTES

1. *Federal Register*, Part VII, Department of Labor, OSHA, "Identification, Classification and Regulation of Potential Carcinogens" Jan. 22, 1980, pp. 5198.
2. *The Report of the Designation of Vinyl Chloride in Ontario*, Ministry of Labour, 1981.
3. Harding, Douglas, "Health Effects of Formaldehyde", *Occupational Health in Ontario*, 3, (April 1982) pp. 64-80.
4. Perera, F. and C. Petito, "Formaldehyde: A Question of Cancer Policy?" *Science*, Vol. 216, June 18, 1982, pp. 1285-1291.
5. As reported in Roderick, H., "An Alternative To Risk-Benefit Analysis in Government Decision Making About Chemical Carcinogens", in Nicholson, W. ed. *Management of Assessed Risk for Carcinogenesis*, New York Academy of Sciences, N.Y. 1981, pp. 233-244.
6. Grawey, R., "Carcinogens Should Not be Protected Under 'Trade Secrets' Umbrella", *Occupational Health and Safety*, May/June 1978, pp. 24.
7. Lemen, R., Testimony before the Royal Commission on Asbestos, July 8, 1981, pp. 93.
8. Acheson, E.D., Testimony Before Royal Commission on Asbestos, July 28, 1981, pp. 112.
9. Linton, H., Testimony Before the Royal Commission on Asbestos, May 28, 1982, pp. 108.
10. Enstrom, J.F. *Journal of National Cancer Institute*, 62, 755 (1979) as reported in Epstein, S. and J. Swartz, "Fallacies of Lifestyle Cancer Theories," *Nature*, Vol. 289, January, 1981, pp. 127-130.
11. Armstrong, B.K. and R. Peto, *Int. J. Cancer*, 15,617, (1975) as reported in Epstein S., *op. cit.*, pp. 128.
12. Wagoner, J. and Infante, P. and Bayliss, D., *Envir. Res.*, 21, 15, (1980) as reported in Epstein, S., *op. cit.*, pp. 128.
13. As reported in Epstein, S. "The Politics of Cancer: With Particular Reference to the Inflationary Impact of the Failure to Regulate", as presented to Lost in the Workplace: Is there an Occupational Disease Epidemic?, OSHA Conference, Chicago, Sept. 13-14, 1979.

14. Harris, R.H., R. Nicholas, and P. Milvy, "Reducing Environmental Risks", *Society*, March/April, 1981, pp. 15-20.
15. Barth, Peter, *Workers Compensation and Asbestos in Ontario*, a study prepared for the Royal Commission on Asbestos, 1982, pp. 6.37.
16. Bridbord, K. et al., "Estimates of the Fraction of Cancer in the United States Related to Occupational Factors, NCI, NIEHS and NIOSH, Sept. 1978.
17. As reported in Epstein, S., *The Politics of Cancer*, Anchor Books, N.Y., 1979, pp. 106.
18. As reported in Epstein, S. *op. cit*.
19. *Ibid*., pp. 108-9.
20. Lavine, M. "Industrial Screening Programs for Workers", *Environment*, June, 1982, pp. 26-38.
21. *Dofasco Study*, submitted to Ontario WCB.
22. EPA, *Inventory of Chemical Substances*, 1979.
23. Jellinek, S., "On the Inevitability of Being Wrong". in Nicholson, W., *op. cit*., pp. 43-47.
24. As reported in Epstein, S., *The Politics of Cancer*, pp. 310.
25. *Federal Register*, op. cit., pp. 5198.
26. "NCI Draft Memorandum to FDA on Use of Animal Data in Cancer Risk Assessment", April 5, 1979, *Chemical Regulation Reporter*, Vol. 3, 8, May 25, 1979. pp. 274-5.
27. Ashford, N. "Alternatives to Cost-Benefit Analysis in Regulatory Decisions" in Nicholson, W., *op. cit*., pp. 129-137.
28. Federal Register, *op.cit*. pp. 5239.
29. "The Macroeconomic Impact of Federal Pollution Control Programs, 1978 Assessment", submitted to the EPA and the Council on Environmental Quality, Data Resources, Inc., Jan. 1979.
30. Crandall, R.W., "Federal Government Initiatives to Reduce the Price Level", *Brookings Papers on Economic Activity*, 1978, pp. 400-440.
31. *Occupational Health and Safety: A Training Manual*, OFL, pp. 4, information from Labour Canada.
32. *Ibid*., pp. 4.
33. Smith, James, Assist. to the International President of the United Steelworkers of America, Transcript. 6005-9.

ONTARIO HOSPITAL ASSOCIATION

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December 7, 1982

Dr. Fraser Mustard
Chairman
Advisory Council on Occupational
Health and Occupational Safety
400 University Avenue
TORONTO, Ontario
M7A 1P7

Dear Dr. Mustard:

Enclosed is the submission of the Ontario Hospital Association in response to the Advisory Council's Discussion Paper on "The Control of Workplace Carcinogens."

The staff of the Hospital Occupational Health and Safety Services, also participated as a member of the Council of Safety Associations in the preparation of their response. The Ontario Hospital Association wishes to endorse that submission, as we believe it closely reflects our own.

We value the opportunity to make comments on these issues. Questions on the attached submission should be directed to the Hospital Occupational Health and Safety Services, of this Association.

Yours sincerely,

Gordon R. Cunningham
Executive Director

GRC/db

Enclosure

Ontario Hospital Association

December, 1982

INTRODUCTION

The Ontario Hospital Association (OHA) represents about 350 hospitals, allied health institutions and agencies, and is their collective voice in all matters related to their operation. The affairs of the Association are governed by a Board of Directors comprising hospital trustees and chief executive officers from all regions of Ontario. Founded in 1924 as an independent, non-profit, voluntary organization, OHA seeks to provide its membership with a wide range of representational, educational and administrative serices, functioning through Board committees, special interest sections, and a full-time staff of over 100.

The Association's Hospital Occupational Health and Safety Services (HOHSS) is a department which functions as one of the nine Safety Associations in Ontario and is funded by the Workmen's Compensation Board (WCB). Serices are provided to all facilities in Rate 882 of the WCB. This includes hospitals, nursing homes, homes for the aged and other health care facilities.

It is a basic philosophy of all these facilities to provide the safest possible environment for their employees no less than for patients and visitors. The proposed regulation of carcinogens would affect hospitals the most however because of the highly technological aspects of patient care.

We support the general concept of identification and classification of carcinogens among the many new chemicals coming into use in the workplace, as outlined in the April 7, 1982 publication *Report of the Special Advisory Committee on Carcinogens*.[1] However, we find some areas of disagreement with the approach taken in the Advisory Council's Discussion Paper, in relation to the identification and classification of chemical substances in the workplace.

The whole idea of looking at carcinogens in the workplace in isolation from other carcinogens is one about which we have reservations. The effects of the carcinogens in the workplace cannot be separated from those induced by exposure to carcinogens found in the community environment or due to lifestyle habits such as smoking. Some of these effects are additive, others synergistic. Therefore, lifestyle and environmental exposures must also be taken into account. We suggest that these issues must be discussed in the context of all the risks which surround an individual working and living in the environment of the 80's.

While OHA agrees with the concept of identification, classification and control of carcinogens, we believe that socio-economic factors must not be forgotten. In our opinion, the Discussion Paper does not give adequate attention to these factors. Initiative and growth could be stifled if these constraints on new products and processes are too heavy.

For easy reference, we attach as an Appendix a copy of "Issues for Consideration" from the Discussion Paper*; and we propose to discuss each issue in turn under its appropriate number and title, with prefix DP to identify it as being from the Discussion Paper.

DP ISSUE #1 — National and International Co-ordination and Co-operation in the Control of Carcinogens

OHA believes it is desirable that a carcinogenic control program should be undertaken on a *national* basis. In the first place, it is questionable whether a provincial government would have any jurisdiction over multinational companies who manufacture and import substances from outside the province. In the second place, independent action on the part of the government of Ontario in controlling carcinogens and suspect carcinogens would be of limited effect, and could have potentially serious and disruptive economic implications if the proposals for regulation were not co-ordinated with existing and anticipated regulatory schemes at the federal and other levels.

In addition, we believe there must be *international* co-ordination and co-operation, so that one country can use evidence developed in another. When there is no mechanism for an international exchange of information, workers in some countries may continue to be exposed to hazards after carcinogenicity has been recognized elsewhere, as in the case of beta-naphthylamine (page 151 of the *Report of the Special Advisory Committee on Carcinogens*).[2] International agencies already exist for the purpose of research into carcinogens; for example, Canada has representation on the International Agency of Cancer Research.

We recommend that the Advisory Committee (see DP Issue #2) be responsible for advising which national and international organizations would be the most appropriate ones to approach for information and/or action.

Any federal control program should include nation-wide adoption of a standard labelling system, and we are pleased that work on this has already begun through the Canadian Standards Association. We further recommend that every effort be made to gain agreement on an international hazard symbol for carcinogens.

DP ISSUE #2 — Advisory Committee(s)

OHA agrees with the concept of a provincial Advisory Committee to advise on actions at the provincial level. We believe it should remain strictly advisory and not be given any power of enforcement. We believe it should remain outside the political arena. We see its mandate as including responsibility for advice on national and international co-ordination and co-operation, and recommend that the Committee members be recognized scientific, occupational health or other experts with credibility in their professional fields.

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*See Discussion Paper pages 1 to 34 of this volume.

DP ISSUE # 3 — Reporting Requirements for New Chemicals

We support, in principle, the establishment of reporting requirements for disclosure of possible carcinogenicity of any new chemical to be introduced into the workplace.

DP ISSUE #4 — Testing Requirements for New Chemicals

OHA would, in principle, also support the establishment of procedures to examine all new chemicals on the basis of chemical structure and relationship to known carcinogens, but we believe economic realities in Ontario must be taken into account. Since it is now generally accepted that only 4% of total cancers are occupationally induced,[2] is society going to be willing or able to pay millions of dollars for a program which, at best, might reduce the incidence of cancer by 4%? OHA does not have the answer to that question but recommends that more research be undertaken as to the cost and time factors involved in the routine examination of all new chemicals.

DP ISSUE #5 — Testing Procedures

We have some misgivings about the testing procedures presented in the Discussion Paper. The limitations of some procedures are very obvious and the regime outlined on page 31 of the Discussion Paper is somewhat inflexible — no allowance seems to be made for rapid advances in knowledge about cancer and in the technology of testing.

The area of testing procedures is one which OHA believes demands an international program, with procedures that are recognized and accepted internationally.

We believe these tests must be carried out on commercial rather than purified preparations because the impurities present in the workplace chemicals may have a carcinogenic effect of themselves.

The testing requirements should be reviewed when it becomes evident that existing programs need updating or are shown to be inadequate. The Advisory Committee could play an important role here, provided its membership had scientific and other professional expertise, as suggested under DP Issue #2.

DP ISSUE #6 — Classification of New Chemicals

The Discussion Paper never defines "carcinogen" and we find this a serious omission. Without a definition clearly stated, the categorization is meaningless in scientific terms. OHA recommends the inclusion of a definition, such as that advanced by the American Conference of Governmental Industrial Hygienists and widely accepted among occupational health and safety professionals.

The categorization of substances into carcinogens (I), suspect carcinogens (II), and non-carcinogens (III), appears almost too simplistic.

We have concerns about Category II because of the statement on page 14 of the Discussion Paper: ". . . if members of the Committee had any doubts whatsoever about the safety of a substance, the appropriate recommendation would be to place it in Category II." This criterion could mean that Category II will become the "dumping ground" for any chemical about which there is incomplete data. It is even possible that Category III will disappear. OHA would like to see a definition for Category II that would be less vague.

The Advisory Council should reconsider its categorization proposal with these concerns in view.

DP ISSUE #7 — The Control of New Chemicals

As a general principle OHA would welcome substitution of carcinogens by non-carcinogens wherever possible. However, we would suggest that the determination of the need for a substitute and the naming of the substitute, should not be subject to government regulation.

With known carcinogens, the ALARA (As Low As Reasonably Achievable) principle should be adhered to, and maximum allowable exposure levels should be set. With suspect carcinogens, permissible exposure limits should be set after consultation with appropriate agencies and organizations. With both types, engineering controls should be operating at the workplace to ensure the permitted limits are not being exceeded, but consideration should be given to personal protective equipment as an option in certain situations.

With regard to epidemiological surveillance, we support the keeping of records for workers exposed to known carcinogens, but we believe there will be some difficulty with data collection for suspect carcinogens. In our opinion, use of non-carcinogenic substances should be permitted without any mandatory surveillance or restriction requirements.

DP ISSUE #8 — The Testing and Classification of Chemicals Not Considered New

To determine which substances on the EPA list, or currently in use in Ontario, have not been adequately assessed for their potential carcinogenicity, would appear to be a long-term project, and it would seem essential to set some priorities. There are approximately 11,000 items currently in the list. To classify and test this number within five years would be to attempt the impossible. We believe it will take much longer than that.

While it seems reasonable that manufacturers or importers should bear the cost of testing, we doubt that the provincial government has jurisdiction over foreign manufacturers and importers. If the program were international and applied to all carcinogens rather than to occupational ones only, there would be a greater chance of getting the manufacturers or importers to accept the cost.

DP ISSUE #9 — The Control of Chemicals Not Considered New

In new plants, whether the chemicals classified as known carcinogens are new or not new, resources could be put to better use if they were channeled into controlling the work environment rather than into elaborate testing programs.

In existing plants, both new and not new chemicals classified as suspect carcinogens should ideally be subject to similar controls as in new plants, but economic realities may necessitate a "phase-in" approach in existing plants.

It is OHA's position that eventually all users of chemicals which are not considered new must be required to meet the standards set out for new chemicals. However, we think five years may be an unrealistic timespan.

Our underlying concern in relation to this issue, is that we are uncertain as to what the regulatory controls might require, and therefore, we find it difficult to respond in any great depth.

We would suggest that suspect carcinogens would need to be subjected to less stringent controls that known carcinogens. Also, controls for suspect carcinogens may need to be in place for a specified period of time only.

DP ISSUE #10 — Epidemiological Survey

Appropriate epidemiological surveys should be provided where individuals have been exposed to known carcinogens. We would suggest the development of guidelines on a national basis to ensure standardization of data collection.

We consider it advisable to have the employers maintain or establish group and individual exposure records suitable for epidemiological surveillances.

The continuation of the Ontario Cancer Registry would appear to be a good idea. However, since it includes records which are relevant to more than workplace carcinogens, we suggest that the funding be such that others besides employers be required to contribute.

DP ISSUE #11 — The Provision of Information to the Work Force and to the Public

OHA recommends that any information for the joint health and safety committees or members of the work force should be limited to simple data presented without technological baggage. A treatise on potential hazards, accompanied by drawings of chemical structure, is often more frightening than enlightening. The information systems should be left to each individual employer, taking into consideration the nature of the work and the work force. We support the ideas of a national labelling and colour coding system to alert people to the presence of a carcinogen or suspect carcinogen in any substance, and a national categorized index of new substances, which would be available to the public. We think the public should have access to the data base leading to this categorization.

The confidentiality provisions of Section 34(1)(b) of The Occupational Health and Safety Act, 1978, should apply.

DP ISSUE #12 — Penalties for Non-compliance with the Regulation

If a penalty is necessary (as at times it may be), the penalties as outlined in Section 37(1) of The Occupational Health and Safety Act, 1978, would be sufficient. The protection from civil liability under The Workmen's Compensation Act should not be withdrawn.

DP ISSUE #13 — Research

It is not our intention to suggest that research personnel should be exposed to avoidable risks, however, there may have to be some provision for the relaxation of regulatory requirements in order to permit research for the development of new chemicals and for medical research. Hospitals have a special interest in medical research and are often the site of experimentation. However, it has been OHA's experience that researchers working with chemicals for scientific or therapeutic purposes are highly trained professionals who are aware of the potential hazards and of the precautions that must be taken. For this reason we believe it would be a regressive step to subject such chemicals to the regulations relating to new substances in the workplace.

FOOTNOTES

[1] Report of the Special Advisory Committee on Carcinogens. Extract from the Fourth Annual Report of the Advisory Council on Occupational Health and Occupational Safety 1981-1982. Ontario Ministry of Labour, April 7, 1982.

[2] Doll, R. and Peto, R.: The Causes of Cancer: Quantitative estimates of avoidable risks of cancer in the United States today: The National Cancer Institute 1981, 66:1911-1308.

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FILE NO: 103.0121 T-2
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Dr. J.F. Mustard
Chairman
Advisory Council on Occupational
Health and Occupational Safety
400 University Avenue
TORONTO, Ontario
M7A 1T7

Dear Dr. Mustard:

We have reviewed the Advisory Council's discussion paper, "The Control of Workplace Carcinogens", and offer the attached comments for your consideration.

We would welcome the opportunity to expand on our main areas of concern whenever it is mutually convenient.

Yours truly,

R. Wilson

R. Wilson
Director
Health and Safety Division

JR:jw

Attach

c: Mr. T.E. Armstrong, QC
Dr. A.E. Robinson

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Ontario Hydro

October, 1982

1.0 GENERAL COMMENTS

In general, we agree with the overall program outlined in Section II of this paper. In particular, the rules presented (see Exhibit I attached) form the basis for a good decision making system respecting the control of workplace carcinogens (subject to the inclusion of modifications based on our comments in this submission). We have some concerns about the principles which will influence the interpretation of these rules and some comments on the procedures proposed for implementing the program.

These concerns will be addressed in some detail in the following sections, but can be briefly summarized as follows:

- Risk from carcinogens in the workplace cannot be considered in isolation from other workplace risks.

- Carcinogens, unlike men, are *not* all the same under the law, because they exhibit a very wide range of potencies.

- It is important that controls take into account current or intended use, number of users, number exposed, extent of exposure, amount used, and type of process on which the risk assessment was based.

- It is important that this topic be approached in an integrated national manner rather than individually by province.

2.0 RISK

In part I of the Discussion Paper it is not clear what principles are being recommended as the basis for the system. In this regard, the following comments are offered.

2.1 The Concept of Zero Risk

In the case of carcinogens, risk is the product of the material's potency as a carcinogen and the level of exposure in terms of the quantity of the material and the number of people involved. The only way for risk to equal zero is if either the potency and/or the level is equal to zero. In the former case the material is not a carcinogen and the concept is redundant.

In the latter case, since there is a finite probability of failure for any barrier, the level of exposure is zero only if the material in question is not present. The material will not be present if it is banned, which is a decision that would be made based upon an estimate of an associated non-zero risk. Again, the concept of zero risk is redundant and, in fact, incorrect.

Further, the consequent risk to humans associated with the intended use of the material depends on whether the new material represents an improvement over current risks.

2.2 Benefit vs. Cost

The following statements are taken from the subject paper:

- *It is argued that no benefit to society can be worth subjecting a work force to a risk which we are unable to quantify at this stage.*
- *The need for a rational and integrated system for identifying, assessing, and controlling cancer risks (both those associated with current practices and the potential hazards of new chemicals) is widely accepted.*
- *The lesson which emerges from such a debate is that in establishing controls for new substances, estimates of risk will generally have to be made without the assistance of epidemiologic data.*

It is a matter-of-fact that nothing in man's environment is completely innocuous and, as a corollary, that everything properly employed can be turned to man's advantage. A test of carcinogenicity addresses only one characteristic of a material, and that without absolute certitude, which in addition may be only one element in the cost parameter of the cost/benefit equation. Surely the system cannot be "rational" if the "cost" of the alternate is not taken into account, assuming that there is some purpose for the introduction of a new chemical.

The discussion paper has itself addressed the first statement quoted above in that the categorization as a carcinogen is the first level of quantification.

The error with the greatest potential for disaster will not be in underestimating the level of potency but in mistakenly categorizing a carcinogen into category III (non-carcinogen) and giving the user a false sense of security. There is no doubt about the benefit to society of doing this categorization, in spite of the risk of error due to the uncertainty in the absence of epidemiological data. (This will be a "cost/benefit" decision on the part of the Ministries involved.)

It should be pointed out that the proposal to relax regulatory requirements for research or "other activities" is in fact a cost/benefit decision. However, it is difficult to understand, why higher risks will be accepted for a graduate student than for a worker in industry without an assessment of the expected benefits.

2.3 ALARA

In a rational and practical sense, except in the redundant cases explained in Section 2.1 above, there is some finite risk associated with a material, or the associated decisions respecting that material. The choice is between levels of risk, type and severity of impact and degrees of certainty. Society may bias the decision against carcinogens in favour of a more acceptable form of impact. Economics will certainly constrain the amount of reduction in risk that society can afford since lowering the level of risk will be subject to the law of diminishing returns. It must also be decided if a given amount of resources is better spent elsewhere, ie the relative benefits of a choice of actions.

All of these concepts are embodied in the ALARA principle (risks as low as reasonably achievable, social and economic factors being taken into account), and apply whether or not the material under consideration is new or already present in the workplace. In fact, all of these concepts are "widely accepted", as indicated in the subject paper, and we recommend that the ALARA principle be explicitly endorsed as the governing principle.

3.0 CATEGORIZATION

As expressed in the proposed "decision rules" (Exhibit I attached), account should be taken of the risks in deciding upon the appropriate regulatory controls for a material.

The following are a few quotes derived from a brief look at the literature regarding the regulation of carcinogens:

A regulatory mechanism is needed to fit response to degree of hazard, a strong carcinogen should not be controlled in the same way as a slight one. Wodicka, V.O. "Discussion of the Regulation of Carcinogens", Risk Analysis, Vol. 1, No. 1, 1981.

For the carcinogens that are deliberately added to our food or used in agriculture or manufacturing, we could avoid exposure, but do not always choose to. Sodium nitrite protects cured meats from Clostridium botulinum which causes botulism; pesticides protect our food, drugs alleviate some symptoms while presenting the possibility of terrible side effects. We live in a risky world where we cannot escape carcinogenic contaminants and do not choose to escape all the carcinogens used to control pests, alleviate symptoms, or enhance our standard of living.

Rather than an emotional appeal to ban carcinogens, we need a careful evaluation of the risks of each along with its benefits. Lave, L.B., "Estimating the Risk of Carcinogens", Risk Analysis, Vol. 1, No. 1, 1981.

The variation in potency may be as great as a million to one between different materials (depending to some extent on the definition used for "potency"). A small amount of aflatoxin B1 in the diet (100 parts/billion) gives cancer to a large fraction of the animals exposed, yet the same amount of saccharin in the diet causes no observable effect. To obtain an observable fraction of cancer-affected animals using saccharin requires the use of about 500,000 times more (about 5% of the diet). We are nevertheless concerned with saccharin because it is deliberately consumed in relatively large quantities whereas aflatoxin B1 is an unintentional, and to some extent unavoidable, contaminant. Crouch, E. and Wilson, R., "Regulation of Carcinogens, Vol. 1, No. 1, 1981.

The potency of materials as carcinogens is a continuum with a very large range. In fact, the errors associated with the testing, interspecies sensitivity variability, and the complication of the multiple causal nature of cancer preclude the existence of a zero on the scale.

Crouch and Wilson have done a calculation for salt, presuming that the animal tests yield a "non-positive" result. Due to the experimental errors associated with these tests and the extent to which salt is consumed, they calculate a potential societal impact (for the U.S.A.) of 14,000 cancers/year.

To quote Crouch and Wilson:

The idea that common salt poses a carcinogenic risk may seem fanciful. But we chose the example deliberately, because it shows that if we try to reduce risks of carcenogenisis to too low a value we cannot do so consistently. An individual risk of one in a million/yr (7×10^{-5}/lifetime, is about as low as is sensible to demand (notice that the average annual individual risk in the above case is 10^{-5}/yr, but this would not be uniformly distributed in age), and higher risks may be acceptable if there are compensatory benefits.

Thus, the categorization scheme suggested in the paper may be too simplistic; and certainly the proposal to make such a decision based solely on an estimate of potency from laboratory tests without considering the second half of the risk equation is surely disaster prone.

Crouch and Wilson suggest the following method for assessing the risk of materials:

1. An immediate rough risk analysis based on reasonably cautious (pessimistic) assumptions about exposure (dose) and an a priori probability distribution for potency (modified by any data which are available in specific cases).

2. A selection of those in which the calculated risk is grater than 10^{-6}/yr, and/or the societal impact is greater than 10 cancers/yr at the 98th percentile U.S. population.

3. A listing of these in order of individual risk for priority attention.

4. A careful look at those, starting at the top of the list, to see if:

- *a) there are groups of people of significant size with a higher exposure,*
- *b) existing data (on mutagenesis, metabolism, or biochemical similarity) can modify the a priori probability distribution for carcinogenic potency in specific cases, or*
- *c) there are quick, easy tests which might improve the information available — mutagenesis tests in vitro or in vivo, short-term animal tests, previously performed human epidemiologic studies for example.*

5. A reordering of the list to take account of any improved risk assessments (in some cases improved information may only make a small difference — for example, the material may be known to be so acutely toxic that animal tests for carcinogenicity have very low sensitivity, and if the risk estimate is already too high to allow its use, the animal data would not change that conclusion even if negative).

6. A further reordering of the list on the basis of the cost of exposure reduction, for it would be useless having further information if the cost of *reducing the exposure were so great or so small that one would not change one's action on the basis of any new information.*

7. For each member of the list, design the tests to be performed to achieve the sensitivity required, applying any cost limitations.

In conclusion, the proposed category I represents a wide-range of possibilities and should probably be further divided based on type of intended use of the material, human exposure pathways, degree of conservatism due to uncertainties in the parameters, critical groups, etc.

Category II is redundant in this system unless it is used as a holding category or for special cases where information is so conflicting as to preclude a decision.

Category III is consistent as long as the criteria indicate that the associated risk is not zero but is less than some calculated value such as 10^{-6}/yr per individual, and a similar standard for the population.

4.0 FEDERAL AND PROVINCIAL ROLES

In a talk given by Dr. G. Atherley to the New York Academy of Sciences entitled "Management of Assessed Risk for Carcinogens: Canadian Issues Involving the Interplay of Social, Political, and Scientific Factors" (March 19, 1980) he said:

Under the British North America Act, the document governing Canadian confederation, the federal government has the power to make laws for the "peace, order and good government of Canada." Most important of these is criminal law. Thus content labelling, interprovincial transport, importation of all substances — all matters crucial to regulating carcinogens — are, at least potentially, areas in which the federal government has the right to make laws. Pre-testing of hazardous substances, for example, could be something the federal government might make law.

Considering that most of Canadian industry and business operates across provincial boundaries it would seem essential that the federal government play a key integrating role in the control of workplace carcinogens. Also, it would seem more practical and cost effective to establish a nationwide carcinogen program. The national program would interface with recognized international bodies and draw upon their experience and knowledge.

Individual provinces should administer control programs in their own jurisdictions according to their need and legislative philosophy. The Ministry of Labour may wish to pay due regard to international agreements in developing the provincial control program. For each of the categories, control should be flexible and based upon the specific considerations of degree of current use, intended use, number of users, number and extent of exposure, amount used, and type of process on which the risk assessment was based.

In conclusion, ACOHOS should recommend that the province formally request the federal government to establish a national program for the testing and categorization of substances for carcinogenic potency.

5.0 COMMENTS ON THE ISSUES

Most of the issues have been addressed either directly or by inference in the previous sections of this submission. A few additional comments follow.

Issue 2 (Page 21) — Advisory Committee
It would be advisable for the national program discussed in Section 4.0 to use an advisory committee due to the complex risk analysis techniques which will have to be used and the judgements which will have to be made on behalf of society.

It seems unnecessary to have a special committee advising the Ministry of Labour on the regulatory program for carcinogens. The normal process for regulating designated substances includes the Advisory Council and allows participation by all interested groups.

Issue 3 (Page 21) — Reporting Requirements for New Chemicals and Issue 4 — Testing Requirements for New Chemicals
To be more cost effective, these requirements should be imposed at a national level, and the extent of all hazards from new chemicals should be disclosed.

If the initial assessment shows a tendency for carcinogenicity, the chemical should be subject to testing requirements.

Issue 5 — (Page 22) — Testing Procedures
Procedures for testing of new chemical agents should be established at the federal level and should be acceptable to the scientific community.

Issue 6 (Page 23) — Classification of New Chemicals
All substances, new and old, should be classified. However, testing may not always disclose that a new substance is a carcinogen or at least a promoter of cancer.

Issue 7 (Page 24) — Control of New Chemicals
7.1 The fact that a substance is hazardous (carcinogenic, etc) does not necessarily imply that specific regulations are necessary. Such a decision will have to be based on the risk involved (ie both sides of the equation).

7.2, 7.3, 7.4, 7.5 Suitable substitutes for a known carcinogen should consider the economic feasibility of substitution, extent of exposure to known carcinogen, and the hazards of the substitute. Permissible exposure limits for all hazardous agents should be established, based on some rational criteria, and exposures kept as low as reasonably achievable.

7.8 If worker exposure to these chemicals is minimized, epidemiological studies are unlikely to provide useful information, particularly where only small numbers are exposed. Epidemiological studies should be undertaken only if justified on a cost/benefit basis.

Issue 8 (Page 25) — Testing and Classification of Chemicals Not Considered New
8.1, 8.5 The Ministry of Labour should determine which substances currently used in the workplace are hazardous.

Information is readily available on the majority of chemicals currently in use.

8.2, 8.3 Testing of new substances and those in current use should be given priority based on, among other things (Section 3 of this submission) quantity used and number of workers exposed. The cost for testing should be borne by the manufacturer or importer of the substance.

8.4 Should not be necessary if 1, 2 and 5 are completed.

8.5 If a national program were undertaken, Ontario could utilize the classifications derived at the federal level.

Issue 9 (Page 26) — Control of Chemicals Not Considered New
See comments contained in Issue 7. There does not seem to be any need to make a distinction in the control requirements applied to old or new chemicals or between existing and new plants.

Issue 10 (Page 28) — Epidemiologic Surveillance
10.1, 10.2 See comment on 7.8 above.

10.3 The Ontario Cancer Registry should be maintained if justified on a cost/benefit basis. Its usefulness would extend beyond the occupational area and therefore would probably be a matter within the jurisdiction of the Ministry of Health.

Issue 11 (Page 28) — Provision of Information to the Workforce and to the Public
11.1, 11.2 Information should be available to workers and the public on the hazards of all substances used in the workplace.

The Occupational Health and Safety Act already gives workers and health and safety committees access to information on hazards, the right to request such information, and the right to refuse work where hazards exist.

11.3 Manufacturers should be responsible for properly labelling hazardous agents. Guidelines for this should be provided at the national level.

11.4, 11.5 The classification of carcinogens should be made public. However, it should not be the responsibility of the MOL to provide information to the workforce. Proprietary information should not be disclosed by the MOL. Confidentiality requirements should apply.

Issue 12 — Penalties for Noncompliance with the Regulation
Penalties contained in the Occupational Health and Safety Act seem adequate and should not be increased.

Issue 13 — Research
Research should be permitted where amounts are less than 1 tonne. There should not be any relaxation of control requirements for research workers handling carcinogens.

EXHIBIT I

Decision Rules for the Control of Workplace Carcinogens

The following is the list of rules, presented in Part II of the subject discussion paper, that are to guide decisions respecting the control of workplace carcinogens.

Page	*Decision Rule*
10	All new chemicals should be screened and . . . any [that] are found to be carcinogens [shall be regulated in] their application in industry.
11	In deciding upon the appropriate regulatory controls for workplace carcinogens and suspect carcinogens, account should be taken of the risk which each of these agents poses to humans.
13(1)	Where such chemicals were to be marketed in quantities of less than one tonne per annum, they should be subject to limited reporting requirements only, except where the competent authority determined that there was a possibility of high risk due to the manner in which the chemicals were to be used.
13(2)	Where, after the initial assessment, it was determined that the chemical structure of the substance was similar to that of a known carcinogen, where it was known to be subject to tissue accumulation, or where earlier studies suggested that long-term exposure might lead to the development of cancer, the substance should go directly into long-term animal testing, regardless of the quantities to be used.
18	Substances which were not new — ie those on the Environmental Protection Agency (EPA) list or those currently in use in Ontario — should, where appropriate, be subject to the above testing procedures unless sufficient data were already available for them to be accurately categorized.
19(1)	Where a chemical which was not considered new was to be used in a newly-constructed plant, it should be automatically subject to the same testing and classification procedures as employed for new chemicals.
19(2)	After five years all users of such substances, whether in existing or new plants, should be required to meet the standards adopted for new substances.

19(3) Provision should be made for the relaxation of the above regulatory requirements in order to permit research and other activities where appropriate exemptions are warranted.

Prepared by:

Mr. J. Richardson
Senior Technical Safety Supervisor
Safety Policy and Program
Assessment Department

Submitted by:

Mr. R. Wilson
Director
Health and Safety Division
Ontario Hydro

Section on Occupational Health
Ontario Medical Association

240 ST. GEORGE STREET
TORONTO, ONTARIO M5R 2P4
925-3264 (Area Code 416)

December 9, 1982

Dr. J. F. Mustard
Advisory Council on Occupational
Health and Occupational Safety
400 University Avenue
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

The Executive body of the Occupational Health Section of the Ontario Medical Association has had the opportunity to examine the Report of the Special Advisory Committee on Carcinogens and the discussion paper.

The Executive members had the opportunity, in addition, to review the submissions on this subject made by the Canadian Chemical Producers' Association, C.I.L. Inc., and the I.A.P.A. to your Council. They are in general agreement with the observations and alternative suggestions made in these three submissions.

We would endorse the above submissions and will not repeat in volume the conditions already stated. We would strongly suggest that the present framework of legislation in respect to the designated substances identification and regulation provides a suitable and effective method for control of workplace carcinogens.

Yours truly,

J. P. Gracie, M.D., C.C.B.O.M.
Chairman, Section on Occupational Health
Ontario Medical Association
123 Eglinton Avenue East
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JPG:rs

THE ONTARIO MEDICAL ASSOCIATION IS THE ONTARIO DIVISION OF THE CANADIAN MEDICAL ASSOCIATION

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JAMES M. HUGHES
Executive Director

(416) 364-9301

October 28, 1982

Dr. J. F. Mustard, Chairman
Advisory Council on
  Occupational Health & Safety
Ministry of Labour
400 University Avenue
Toronto, Ontario M7A 1T7

Dear Dr. Mustard:

The response of the Ontario Mining Association to the Advisory Council's discussion paper titled "The Control of Workplace Carcinogens" is in two parts.

The first part makes five fundamental or philosophical points on the Advisory Council's approach to the subject. The second part was prepared by Falconbridge Limited, a member of the Association.* The Association endorses the comments in this submission.

As an appendix we have attached a copy of the transcript of the testimony of Dr. James Ham to the Select Committee on Ontario Hydro Affairs. We have referred to this testimony in our submission.

The Association notes with approval the Advisory Council's initiative in publishing a discussion paper for comment prior to preparding recommendations for the Minister of Labour.

Yours very truly,

JMH/eok
J. M. Hughes

* See page 272 for Falconbridge Ltd. brief

Ontario Mining Association

October, 1982

The staff of the Ontario Mining Association has reviewed the Advisory Council's discussion paper titled "The Control of Workplace Carcinogens."

Council quite rightly identifies the issue of cancer as a highly emotional one; it is almost impossible to be coldly rational when considering such an insidious disease.

On the other hand, it is vitally important to the people of Ontario and Canada that leadership be provided in developing priorities in issues of health and safety.

The comments made by Dr. James Ham to the Select Committee on Ontario Hydro Affairs on July 22, 1980 are worth reviewing. The point he was making was that scientists must clearly evaluate the risks of various human activities, and that political leaders must make decisions. Statesmanship is required. Short term, self-serving decisions do not strengthen society. For the convenience of the Advisory Council, we have attached a copy of the transcript of Dr. Ham's presentation.

The five fundamental points the Association wishes to make are:

1. Since, as Council has stated, the health of an individual "is the product of his or her genetic characteristics interacting with the environment and the individual's lifestyle," it is not logical to consider workplace carcinogens isolated from other carcinogens. The example of an asbestos worker given in the report of the Special Advisory Committee on Carcinogens (on Page 160) suggests that smokers should not be hired for asbestos exposures. However, Council ducks this issue.

We are rapidly approaching the point where people have to choose between keeping their lifestyle or their jobs. It may be possible to reduce the rate of lung cancer in asbestos workers to something less than the 5.2 factor that the Special Advisory Committee quotes but surely it would be more appropriate to reduce the cancer rate factor from 53 to 5.2 simply by not hiring employees who smoke. This requires a high degree of participation and commitment from employees and employers, scientists, governments and the public at large.

The challenge for society is to reduce the incidence of cancer, whether workplace or lifestyle induced. To paraphrase Dr. Ham in his report on health and safety in mines, it will require the above parties to operate as a system.

2. We agree with the concept of "acceptable risk." Dr. Ham also commented on this concept to the Hydro Commission.

3. Part IV of the Occupational Health & Safety Act, 1978, deals with toxic substances and uses the phrase "likely to endanger the health of a worker."

We believe that this adequately defines carcinogens and therefore detailed special regulations for carcinogens are not necessary. Experience may indicate that interpretation documents are required.

4. Council, on Pages 17 and 18 of the discussion paper seems to be suggesting that if management fails to do what the law requires, workers should have the right to ask the government to impose a financial penalty, or that management should lose its "protection from civil liability under the Workmen's Compensation Act . . ."

We believe this type of procedure was dealt with summarily by Mr. Justice McRuer so that the rule of law was firmly established in Ontario. Only courts interpret law; only courts impose financial penalties under the law.

The suggestions being made by Council on this matter are diametrically opposed to the fundamental rules of justice.

5. We agree completely with Council in its efforts to have economic impact assessments produced as part of the general process of risk assessment. This procedure should not be viewed as a mechanism to block progress but as an integral part of the priorizing process.

The staff of the Association is in full agreement with the Council that strenuous efforts must be made to control workplace carcinogens. We know that these efforts are being made in the mining industry in Ontario.

However, since cancer is a product of genetic characteristics, environment and lifestyle, since control measures are influenced by social expectations and concerns, and since the social costs are the same for a worker who succumbs to vinyl chloride exposure, smoking, a fall from a building, or a traffic accident, the scientific community should exhibit leadership by assessing and priorizing the risks away from an emotional atmosphere.

Since the economy cannot support an all-out attack on all the problems facing our society, it is absolutely vital that our political leaders have available to them properly done risk assessments and economic impact assessments so that they can explain to the general public the rationale for their decisions.

LEGISLATURE OF ONTARIO

SELECT COMMITTEE ON ONTARIO HYDRO AFFAIRS

TUESDAY, JULY 22, 1980

The committee met at 10:14 a.m. in room No. 151.

MINING AND REFINING OF URANIUM ORE
(continued)

Mr. Chairman: The committee will come to order. As usual, staff has some filings and then we can proceed.

Mr. Schwartz: Before we begin this morning, I would like to make one other minor change to your schedule. On the schedule as it now appears, on Wednesday, August 6, at 10 a.m., we have Rio Algom and at 2 p.m. we have Denison Mines Limited. On Thursday, August 7, as it now appears, we have Ralph Torrie at 10 a.m., and at 2 p.m., representatives of the United States Nuclear Regulatory Commission. We are switching it so that on August 6 at 10 a.m., the United States NRC witnesses will be here. At 2 p.m. on that same day, August 6, Ralph Torrie will appear before you.

Mr. Bounsall: These are in place of those that were scheduled.

Mr. Schwartz: That's correct. These people were simply scheduled on the 7th. They are being moved to the 6th and their order reversed.

On August 7 you will have the witnesses that were originally scheduled for August 6 in the same order: at 10 a.m., Rio Algom and at 2 p.m., Denison Mines.

Just very quickly, on August 6 in the morning, the NRC; in the afternoon, Ralph Torrie. On August 7 in the morning, Rio Algom; in the afternoon, Denison Mines.

I would like to read a few documents into the record as well. These are documents which I hope you all have. They were handed to us during our visit up in Elliot Lake. The first to be marked is exhibit G-14, Submission of the United Steelworkers of America to the Select Committee on Hydro Affairs, dated July 16, 1980, from Elliot Lake, Ontario.

The presentation of the Serpent River Indian band at Elliot Lake, which has the title "Select Committee on Ontario Hydro Affairs" on it, will be marked as exhibit G-15.

G-16 is a one-page document entitled Denison Training Facilities that was handed to you during our tour of the Denison facilities.

Exhibit G-17 is entitled Denison Mines Limited, Existing and Proposed Mill Circuit.

Finally, G-18 is entitled Denison Mines Limited, Tailings Management. On the first page it has a number "1" and the word "General."

This morning, the first witness who will appear before us is James Ham who, as you all are aware, was the commissioner who was responsible for the report of the Royal Commission on the Health and Safety of Workers in Mines, which has been marked as exhibit G-2. Dr. Ham, would you come forward to be sworn by our chairman.

Dr. Ham sworn.

Mr. Schwartz: Dr. Ham, as you are all aware, is currently the president of the University of Toronto and has gone to some difficulty in appearing before us. I am sure his testimony this morning will be of some significance to us. Dr. Ham, our usual procedure in this committee is for the witness to proceed with his comments and the committee will interrupt for explanatory questions and otherwise as you proceed and then we will ask questions at the end of your presentation. Thank you, sir.

10:20 a.m.

Dr. Ham: Mr. Chairman, gentlemen, it's a pleasure for me to come and be with you this morning.

Since I had the privilege of being a commissioner for the report on the health and safety of workers in mines, I have not personally been intimately involved in the issues. I have a view that a commissioner, given the privilege of probing into other people's business, should make his report and leave the issues for those who have a continuing responsibility for them. I have continued to have a personal interest in the general human problems that are involved in issues of health and safety, and I would like to make some brief comments from that perspective, and then be at your service.

The first thing I would like to do is to try to set mining in the broader perspective of all the technological activities that we engage in as human beings and observe that perhaps one of the reasons we're all here this morning is that it's an inherent feature of the technological society that it is self-indicting. By that I mean that as a consequence of building nuclear reactors, of mining and so on we develop a whole associated fabric of technology which includes, in particular, measuring instruments. One of the characteristics of our time is that we can now measure substances in incredibly small amounts. Some of these measuring techniques indeed depend on nuclear research, which is the same kind of nuclear research that has led to the development of reactors.

I would refer particularly to instruments such as nuclear magnetic resonance devices, which permit us to take measurements these days which we couldn't conceive of doing some years ago.

These measurements allow us, for example, to detect toxic substances in minute amounts almost everywhere. It has been jovially said that with the best of modern instrumentation it's now possible to take a glass of water out of anybody's tap and find in it trace amounts of almost every material that has ever existed on the face of the earth. This, of course, tends to scare us.

The second feature of our measuring capabilities is that we can diagnose and measure biological insult to human beings with degrees of specificity that formally were unknown. The third feature is that we can now store information in computer banks and so on, in ways and on a scale that was never before possible. Finally, our media allow us to bring forward almost daily for attention the consequences of these measurements and diagnoses that we are able to undertake. As a consequence of this, we are far more sensitive to the consequences of our technology than we ever have been before.

The next point I would like to make is that risks are everywhere. We all live in a matrix of risks. One of the things I think we all need to be as citizens is more sensitive to the complexity of that matrix of risks.

To give you one or two simple examples, if you are my age in this country your risk of dying from some cause in the next year is about one in 100. By that I mean that if you take all of the Canadians who are my age, one in 100 of us will die this year from some cause.

If you are one of the population of hard-rock miners in Ontario, at least in the period when I was doing the commission study, your risk of dying was about one in 1,000. I don't think on a statistical basis over a period of years that risk has materially changed.

If you are one of those people who drive a tractor-trailer that jack-knifes or is involved in an accident, your risk of dying in the next year is about one in 10,000. As you know, your risk of being killed on a golf course by being struck by lightning is something in the order of one in a million. So there are risks everywhere and what we must do, I think, in addressing specific risks, such as in the uranium industry or any part of man's technological activity, is to see those risks in the context of the whole matrix of risks that is endemic to being human.

Let me remind you that there are really two kinds of risks: voluntary and involuntary. To me, voluntary risks are the risks of lifestyle--the risks of overeating, drinking, smoking, canoeing or of doing any of the things that are characteristic of the word we call lifestyle. Involuntary risks are risks that we experience because we do things together, because we do them collectively and socially, for example, risks that result from riding on public transportation systems, using public water supplies, taking employment at work. In addition to that, there are involuntary risks related to the natural environment--storm, pestilence and so on.

These two kinds of risks, voluntary and involuntary, have to be set in balance somehow. We do not tend to set these in balance. Indeed, we tend to concentrate our social attention on very specific involuntary risks, such as the ones you are investigating. In particular, for the nuclear industry we tend to concentrate on particular involuntary risks and not to set those in the context of related involuntary risks or voluntary ones. There was a remarkable paper written about 1969 by Chauncey Starr at the University of Los Angeles in California, in which he demonstrated on the basis of a statistical analysis of risks that had been experienced in at least the US society that you and I will undertake voluntary risks on the order of 1,000 times as large as we will permit anyone to impose involuntary risks on us.

Mr. Williams: Dr. Ham, could I just interrupt? Do you classify choice of the work place as a voluntary or involuntary risk?

Dr. Ham: That is an interesting question. I classify working risks as being involuntary simply because in our society it is natural and necessary to work to sustain a family. I regard the risks of occupation as being involuntary. One really does not have a choice whether to work or not to work. Unemployment is a risk of not having freedom to have work. But I regard occupational work as involuntary risk.

Mr. Williams: Per se, but the choice of where you will work must surely be voluntary.

Dr. Ham: Sure, you can choose to work in the mining industry or, to the extent that you are flexible enough, you could choose to work as a secretary in a TD Bank building. The risk level from those two places is obviously very different. There is an element of choice.

Mr. Williams: That is the voluntary aspect of it.

Dr. Ham: Right. What Chauncey Starr demonstrated is that you and I will impose on ourselves risks many, many times higher than we will permit other people to impose on us. In fact, he used the figure 1:1,000. He used an aphorism which I think we should all learn. He said: "We are loath~~e~~ to have others do unto us what we will happily do unto ourselves." When we talk about risks we do have to understand this because our capacity to be free to engage in the lifestyle of our choice comes about because of our affluence.

10:30 a.m.

I just came back from China. If you travel down the Yangtze River you will easily observe that Chinese do not have many choices of lifestyle. But we have many choices of lifestyle and our freedom to choose comes about because of our affluence which is fundamentally technologically based. When we impose risks on ourselves because of our freedom of lifestyle, we are exploiting the freedoms which are personal, that derive out of the technological productivity of our society.

It is that technologically productive society that is the source of involuntary risks. One of our great puzzles socially is how to decide to strike a balance between the risks that we impose on one another collectively because we build transportation systems, because we mine and so on, the risks that arise from that source, and the risks that arise that we impose on ourselves as citizens. When we think about this issue of what is an acceptable occupational risk, we cannot isolate that question from the fact that we impose risks on ourselves in many, many ways.

Indeed, I think one of the dilemmas of our society is the dilemma between freedom and regulation. One aspect of freedom, of course, is freedom of lifestyle, and one aspect of regulation is the regulation that we undertake to ensure that occupationally imposed risks are as small as are reasonable.

I suggested to you that risks are inevitable and that we ought to be very careful not to dream about a world of zero risk. One of the great social problems to me--and I am sure you realize this at this stage better than I do--the real puzzle, is what is an acceptable risk. That is a very difficult question. Let me calibrate that a bit in terms of the commission study by observing that whereas in the uranium mines there has been a great deal of concern about excess lung cancer, the fact is that in the uranium mines, over the period that we examined them, there were far more life years lost from fatal working accidents than there were as a consequence of the existence of excess lung cancer.

Indeed, the figure I recall was that among the uranium mining population in the years 1955 to 1974, there were eight times as many life years lost or deprived from fatal accidents at work than there were from excess lung cancer. The typical circumstance was that a fatal accident tended to occur among younger people than lung cancer did, so that when someone died from an accident, such as perhaps being crushed by a rock fall, typically 35 years of life were lost. That is to say somebody died at an age when at that time he would have an expectation of life of something like 35 years, whereas when an excess lung cancer case was imputed by workmen's compensation, typically the man at that time had something like 22 years of life expectation.

Mr. Kerrio: Dr. Ham, on that note, will those figures not change as time goes on because of the short span that we have been involved with? Isn't that the reason it is vital for early detection of cancer and treatment?

Dr. Ham: Yes, and may I say that in the presence of Dr. Woollard, who is doing a major update of mortality circumstances among miners, there will be very important information available that will give further perspective to these issues.

Mr. Williams: I just want to clarify one point there. You said the ratio was five to one?

Dr. Ham: Eight to one.

Mr. Williams: Eight times more fatalities than--

Dr. Ham: No. There were eight times more years of life deprived. In other words, if I die from an accident in a mine, say, at 35 years of age, when my life expectation might be 70 years, I would have been deprived of 35 years of human existence; whereas if I were a cancer case I might have died at the age of 50, when I might have had only 25 years of expected life. I am talking in terms of the loss of expected life years.

I say those things, not to argue that either fatal accidents or excess lung cancer is acceptable, but simply to indicate that it's false, I think, in examining the risks of occupation to concentrate on simply one risk. I think it's essential to see what the total pattern of risks is that a person has to face.

I would also like to confirm my conviction that when it comes to deciding--and this is really, it seems to me, what is in part before you people in looking over Hydro affairs, to the extent that you are looking at the question of what kinds of risks are acceptable in the nuclear fuel cycle--you are dealing with a problem that has to be resolved by persons like yourself. Scientists cannot resolve this problem.

Underlying what we are talking about is the question is it legitimate to have somebody's life in some sense shortened? Whether you are driving a tractor-trailer or working in a mine or whatever you are doing, an underlying basic question is, is it legitimate to have somebody's expectation of life shortened because of the nature of his occupation? The answer surely has got to be it is legitimate because we work and we manufacture and we mine. It's this activity, as I say, that gives us our affluence to be a free and choosing society in ways that many other societies are not. But science cannot even put the question is it legitimate for any person's life to be shortened as a consequence of working?

That's a question that is a social question. It has got to be resolved in particular by the political system. I, personally, would like to encourage you in the endeavour that you are engaged in because there is a tendency these days to think that these questions can be resolved by doing detailed research, by calling upon experts. Experts in research can produce information. They can help to set a kind of context of measurement and diagnosis and epidemiology about these things, but the issue as to whether these things are socially acceptable is not a scientific question at all. I want to urge you, as you focus on these questions, to look at the whole matrix of things and not to allow a kind of fragmentation of perception on these things to cause you to concentrate on one thing, one element of the whole matrix of human risk, to the exclusion of all the others.

From the time I had the privilege of looking at this whole question, I was puzzled and remain puzzled about how the worker comes into this whole question of the decision on what kinds of risks are acceptable. Somehow or other, there has to be a kind of equitability about the relationship of the individual to the society. I have, in my own mind, identified three elements of this issue of equitability. The first one of these I call the issue of selectivity. Some risks are concentrated on small populations of people. One of those small populations of course is the mining population, and we all know that the risks in mining are significantly higher, for example, than they are in manufacturing.

So risks are selective in a sense that some industries are innately more risky than others. I think we accept that. Some people choose to work as miners and some people don't. We should observe these things and, in some sense, while we are interested always in reducing risk, we should simply observe this variability and make up our minds that this is an innate part of the kind of technological world that we build for ourselves.

10:40 a.m.

There is a second aspect of equitability which is what I call susceptibility. This is related to the question of whether some individuals are more susceptible to the manifestation of risks than others. For example, among miners do you have a so-called accident-prone subset? Do you have people whose physical stature is such that they are more susceptible to back injury than others? Are there people whose respiratory systems are such that they are more susceptible to insult from sulphur dioxide, nickel carbonyl, or whatever it is?

I know nothing about accident-proneness, but I am quite sure that some of us are more susceptible to injuring our backs than others. My own respiratory system, I know, is not a particularly rugged one. I am particularly sensitive to small amounts of things like sulphur dioxide.

There is an interesting social question about what to do about susceptibility. The first thing is, do you actually detect it? Do you prescreen workers? In mining, there has been a general, sensible kind of screening of workers with respect to the degree of physical exertion that is involved. I personally do not know how you respond to the problem that some people are more susceptible than others. I simply indicate that the whole question of screening of workers, the whole question of informed consent is there. For example, if a worker, in some sense, is judged to be respiratorially more susceptible than others but, nevertheless, wants to work in a relatively hazardous area, there is the question of whether one should have things like informed consent from him, and so on.

The third factor, to me, in achieving some kind of equitability in the experience of risk is simply openness, having working people understand the possible risks in their work. I think we have a long way to go in doing that. One of the difficulties in being more open is, of course, that there is a tendency to concentrate on particular elements of risk which introduces a sense of fear. Nevertheless, I think it is essential that workers should be informed about the basic risks of the circumstances in which they work.

Finally, in terms of this whole business of whether a risk is acceptable or not, I think we have to be honest with one another about what we know and what we do not know. There are many things, at least in my view, about risks, particularly from toxic chemicals, and so on, that we simply do not yet know. In a certain sense, we will always have large areas of ignorance about the possible consequences to us of the many toxic substances we have. Nevertheless, a part of being open is, I think, being honest about our uncertainties. Then, in the end, the issue of what risks will be accepted is fundamentally an issue of social decision and not questions that can be resolved on the basis of research, on the basis of scientific analysis.

I will make one final comment and then I will stop. When we decide what framework of risks are acceptable we will, in the process of doing so, set up certain standards. For example, they may be standards of exposure to radon and its daughters in mining.

When we set up a standard it does not mean that the experience of a given worker is in keeping with that standard. In other words, standards are like regulations, they are a sort of guideline. They do not necessarily mean that the experience any of us has under a standard is adequate. In the end, what is essential in minimizing occupational risks is the quality of working relationship between workers and their supervisors, the quality of their training, the quality of their supervision, and the care and attention that management gives to the whole working process.

I plead an inability, other than to give you these general remarks which are based on the privilege of having engaged in the intensive study of uranium mines some five years ago, and having a continued personal concern about these social issues. I think they're terribly complex. There are no simple solutions. They deserve political attention, and I applaud the fact that you are putting your minds to them.

Mr. Chairman: Thank you very much, Dr. Ham. They may have been general, but they're profoundly useful, at least speaking personally.

Mr. Haggerty: Mr. Chairman, I wanted to address some questions to Dr. Ham. Have you done any follow-up on your 117 recommendations in your 1975 report? Are you satisfied with the present follow-up carried out by the uranium mines in Ontario and by the Ministry of Labour?

Dr. Ham: Mr. Chairman, I have not thought it my business to follow up on what happened to particular recommendations. My sense is that Ontario was then and is now as relatively advanced in its approach to problems of occupational health as most other jurisdictions. My sense is that in Ontario the new act and the new arrangements are typical of similar arrangements that exist in other provinces such as, for example, Saskatchewan, and are similar to arrangements that exist in other countries such as Sweden or the United Kingdom. My general impression is that provincially we are reasonably well organized to tackle these issues. In terms of what has happened with particular issues, I'm not in any position to say.

Mr. Haggerty: Since your report came out in 1975, we can see that the industry has moved in a direction to correct some of the existing problems that relate to occupational health in the mining industry. In fact, the government has moved in this direction, more so than they have in the past. You shed some additional light on the matter this morning, as you pinpointed some of the key recommendations in your report. I thought that perhaps you considered that government, the Ministry of Labour and industry weren't moving fast enough in this area as it related to monitoring of the hazardous areas related to the industry.

Dr. Ham: I simply don't know whether it is adequate or not. I don't attribute this to my work. I think it's characteristic of our time that we are all becoming more sensitive to these things.

It will perhaps not be without some amusement to you to know that one of the areas the new occupational health and safety act has an impact on is the university. We are not without our problems. The university is a place where we probably handle a great range of toxic substances, and we handle radiation all the time. It has to me been a kind of humbling experience to realize that these issues are applicable in our own house. I think the public sensitivity to these issues has risen, and I think that's a good sign. Whether or not the particular organizational arrangements we have and so on are adequate or whether they are performing up to snuff, I'm just not able to say.

My sense is, for example, that the new advisory committee that reports publicly on these issues is a significant step forward; but I am not able to offer you any detailed critique that would represent in a sense any continuation of the kind of probing analysis that a commissioner has the privilege to undertake.

10:50 a.m.

Mr. Mackenzie: The point you make about the number of days lost, or years lost because of injuries, rather than the results that we may not be fully aware of yet in terms of lung cancer or other results of toxic substances, strikes me as being a fair argument in terms of some equality of workers' participation in the program and the current arguments we get over the worker's right to refuse an unsafe operation, or an unsafe job, or what they perceive as an unsafe job. As a result of your looking into this matter, would you have any personal comments on this point?

Dr. Ham: On the right of men to refuse work?

Mr. Mackenzie: That's right.

Dr. Ham: I guess I ought to be frank and say that at the time the commission reported and made recommendations, I did not recommend that a worker have a kind of automatic right to refuse work. I recommended that there be a staged series of investigations necessitated in a circumstance where a worker is basically concerned about the circumstances of his work. While to right to refuse to work is a kind of innate human right to which

I guess I have no fundamental objection, I don't think the right to refuse work in itself solves the problem.

If a worker has--and I accept that he would feel this way--an absolute feeling that some condition of work is unreasonable, then he has every right to have that circumstance thoroughly investigated. If we are going to minimize fatalities or injury, whether we do or not, I don't think what is central to this business is the right to refuse to work, although that is a right to which I have no fundamental objection to, but what is really important is the quality of working relationship between the worker and management, and the whole operation of the circumstances of work, that lead to the minimizing of circumstances in which he would wish to refuse to work in the first place.

The reason I put it that way is that regulations don't guarantee safety. We can have all the regulations in the world and have a very unsafe world simply because people don't abide by them. To me, the right to refuse to work is kind of symbolic of an ultimate right which has no great significance unless what I call the internal responsibility system, which involves the worker and management and the whole sort of social milieu in which industry functions, if that system of people and interests isn't alert enough really to work at the issues that led the man to refuse in the first place. I do not think the right to refuse work is intrinsically any guarantee that things will be safer.

Mr. Mackenzie: What bothers me about that a bit, Dr. Ham, is that you make the point that the decisions that are going to be made are not scientific, they are social decisions. People like ourselves will have to make them in terms of what we are going to do and what we require in terms of safety in the work place, and yet very few of the operations with which I have had any contact--some are better than others--have that adequate relationship between management and the workers.

One of the constant complaints of the workers is the kind of equality they have in decision-making or the kind of input they have into it. One of the things that is focused on is whether, in the whole question of occupational safety, particularly in the mines, the workers do have the right to refuse what they see as an unsafe operation. Without that right they do not see--at least those who have talked to me--equality in decision-making. They also see it as pretty fundamental; maybe not as important as you have related here. That is really why I asked the question as to what your observation was on the matter.

Dr. Ham: It is a very complicated issue which I cannot illuminate any more for you. On the question of who makes decisions, when I say it is a social and political decision, the kind of issue I suppose you are wrestling with, for example, is: Should we have nuclear power? That kind of decision is obviously a social decision.

In the end, for example, on the question of what radiation level is to be accepted, you have to accept some level. I believe very strongly that we are socially illiterate--I say that to myself--about the complexity of the risks of being human.

One of the great dangers in our technological society is that we focus on some particular risk and say, "That one shall be minuscule." Then we turn our attention to another one and say, "That one shall be minuscule." I am now talking about involuntary risks, because I keep on saying regularly that every day you and I impose risks that are thousands of times as high as are imposed on us. Ultimately they can be backed up by science and research but the issue, for example,of the level of exposures we are prepared to tolerate in terms of toxic substances, to me, cannot be answered scientifically. In the end we have to realize there is no risk-free environment. Certain risks will occur and some of these we have to accept.

The question I perceive we are talking about is the whole question of the quality of the working relationship between the people who are engaged in technological activity. I realize that this involves the whole question of unionization and so on. I would simply like to say that whereas the right to refuse work is a perfectly legitimate human right, the existence of it--I repeat--does not ensure safety or a high quality of working relationship. The right may be there but what is really important is the quality of the actual day-to-day working relationship and understanding between the people engaged in the activity.

Mr. MacDonald: Is not the right to refuse to work a legitimate safety valve to cope with the situation in which there is an absence of or an inadequate labour management safety committee? Because an effective labour management safety committee is the mechanism for coping with differences of view with regard to the level of safety and its legitimacy.

Dr. Ham: Sir, I have no difficulty with the notion of a right to refuse to work as an ultimate safety valve for the protection of you or me.

Mr. Mackenzie: Maybe I am being a little bit too specific, but do you have any comments or can you understand the concern regarding the conflict between provincial and federal jurisdiction? Talking once again of workers' rights to refuse, there is a difference between a worker refusing what he perceives to be an unsafe operation and a worker who has a right to refuse in terms of imminent danger. There are those who argue there is no difference. I can tell you it is not the position of most of the workers I have talked to.

Dr. Ham: Has this got to do with the difference between the Canadian Labour Code and the provincial code?

Mr. Mackenzie: That is right. Federally, it is an imminent danger you can refuse, provincially you have the right to refuse if you perceive the situation to be dangerous.

Dr. Ham: I am not acquainted with that.

Mr. Mackenzie: The argument the worker will make may be simplistic, but he has to know that the roof is ready to come down before he can refuse, or it has got to have started to come down before he can refuse. That's the imminent danger.

11 a.m.

Dr. Ham: In any given situation it seems to me there's the issue of making a decision. My own position would be that if a worker really feels that a situation is unsafe, if he's in a mine, he ought to withdraw from it, and there ought to be the focusing of the best attention that can be given on an evaluation of that circumstance.

Mr. Mackenzie: Does it concern you, having done this report, although I recognize you stated you haven't paid that much attention to the follow-through on the various recommendations, that we get a year such as this one where we have such a high accident rate and death rate in the mines--I believe twice or more than last year?

Dr. Ham: I obviously don't know. I would say this much, neither in defence nor in support of public concern on this issue, that we are dealing with statistics. If you look in the report, for example, at the fatality statistics for Ontario and for other provinces, you will see they fluctuate quite dramatically over a space of a few years but there's a trend line on them. I don't know whether the larger number of deaths that I have noted several times in the paper represents a systematic deterioration in the care that's being given to supervision and training and the execution of work or whether it represents the fact that in this particular year it just happens that there are a larger number of deaths.

One thing that one must be very careful about is to observe that there is significant statistical fluctuation year to year. While this may seem a kind of inhuman response, if this increase continued over a period of years, I would be very deeply concerned as to whether it represents, as I say, an actual systematic decline in the quality of training, the quality of supervision, the manner in which machines are maintained, the execution of work. I don't think anybody at this point can in fact decide. I don't think there's enough information available to determine whether that has actually happened, because there are sharp fluctuations in the number of accidents that occur.

Mr. Mackenzie: In terms of our dealing with toxic substances, one of the pushes for taking a look at them was your commission and the report and the subsequent legislation we have ended up with in terms of health and safety. You talked about the advisory committee. Are you aware of the fact that the first six or seven substances that are considered to be toxic and dangerous --asbestos is one of them which we have got an lot of information about--and the proof is overwhelming about some of them, were gazetted better than two years ago.

We not only have not gone through the second gazetting of those as yet, but up until very recently the advisory committee hadn't even had the results back to look at from the hearings on them. We now are having, admittedly with a briefer time to respond, those same seven toxic substances regazetted that were supposed to have been dealt with over a year ago by officials up to the Premier's level. Does this not concern you?

Dr. Ham: Sure. I mean the question of getting on with confirming standards is a good issue. I think it's a good thing that we have in existence now an advisory committee whose report is public so that the public knows what the committee advises, what the minister accepts and doesn't accept. Publicly that's an improved situation in regard to the rapidity and sense of urgency with which standards get set. I am aware that this problem is kind of endemic. In the US, OSHA has been perceived publicly not to be getting on with the task as rapidly as it ought.

Mr. Mackenzie: We have seven substances--and I took the trouble to talk to members of the advisory committee early in June--and at that point in time they had had nothing back for a final decision on any of them. As I say, I see by The Gazette they're being gazetted again now, the original step. I understand the argument is over legalities. But that's two and a half years ago and we're going through the procedure once again. These are seven substances we were to have had regulated almost a year ago.

We had an additional group scheduled for 1979-80 that has never reached the first gazetting stage yet. Many of them are substances found in mines. I really wonder, when we talk about social awareness and the kind of relationship we have between the workers and the companies, whether or not a committee like this doesn't have the deck loaded in terms of the system we're up against. How much influence are we going to be able to have?

You feel a little bit frustrated, even as a member of this committee, when you get the different views on safety matters and the toxic substances, when we find that in a province supposedly as far ahead as you say Ontario is we haven't got to the first single toxic substance regulation yet in Ontario.

Dr. Ham: I am unaware of exactly where these extend to. I can share with you a sense of concern about the rate at which these things get done. One of the things that shocked me--this is now old stuff--is that after 50 years of experiencing the disease of silicosis, the province didn't have a standard on dust exposure. There are two sides to these things. One is the social and public responsibility to have standards, and to me it is as complex as hell as to what the standard actually is.

I think there's a tendency--and I say this frankly--for all of us to want each individual risk to be very small. If we are going to have our technologically based society and thrive on it, since it's customary for government to be a bit provocative and to talk about economic growth, as a citizen one of the things I observe these days is that many people seem to think that all would be well with us if we could just make the economy grow.

If the economy is going to grow on any basis whatsoever, it's going to be technologically more intensive. It's trite to say that. If it's going to be technologically more intensive the risk pattern we generate for ourselves is going to be more complex. I honestly don't think we have socially learned how to resolve the question of what we do.

I think one of the reasons why governments are slow in producing standards is the question of how you set a standard. Take asbestos for example. What is the right standard? Then there's the question of how effectively that standard is achieved in terms of people's experience of that substance. I for the life of me do not personally know how you do that. Should it be two fibres per cubic centimetre or one cr .5? How do you decide what risk in this particular area is socially acceptable as part of the whole matrix?

I could share with you a sense of chagrin that the staff of the ministry don't get on with doing these things. But I would also share with you a sense of puzzlement over how the devil to decide what those particular numbers ought to be.

Mr. Mackenzie: If the decision is a social one, and not a scientific one, would you agree that where you work in the workplace is an involuntary risk that you take, unless the system we live under is able to provide adequately alternative jobs for everybody or alternative occupations?

Dr. Ham: Yes, I agree. I regard occupational risks as involuntary. They are imposed on the worker. A Canadian worker doesn't generally have the freedom of choice to move from a high-risk occupation to a low-risk occupation. That means the risks he encounters are involuntary.

11:10 a.m.

Mr. Mackenzie: Even less if it is a one-industry town or a northern mining town.

Dr. Ham: Sure, absolutely.

Mr. Mackenzie: I did not take your argument this way, although I listened to it carefully, but I take it you are not arguing that we do not have the right to set a much higher involuntary standard than we will accept on a voluntary basis.

Dr. Ham: Sure, we have a right legally to set standards anywhere we like. I think the tendency is for us to set standards with respect to involuntary risks that are very much tougher in a certain overall social sense than we will consider imposing on ourselves with respect to our lifestyle.

Let me quote you something that will provoke. This is a quote by a British epidemiologist, Richard Doll, who first uncovered excess cancer among workers in nickel metallurgical plants in Wales. One of the things we need to remind ourselves is, if we want to talk about cancer among workers, that at least to the time of the commission there were significantly more imputable excess cancer deaths from the metallurgical plants than there were from the uranium mines. That simply illustrates that these problems are not all in one place. But he said this:

"The proportion of cancers in the population as a whole that are caused by agents introduced by industry in the 20th century is minute, and there is no reason to suppose that the application of the most rigorous restrictions would do more than tinker with the real problem that is facing us." His definition of the real problem is, in part, this: "Observations of mortality rates in people with different smoking habits suggested in the absence of smoking the mortality from lung cancer in men would be reduced by 90 to 95 per cent and from all cancers by about 40 per cent."

I quote that, not to argue that we should not have, for example, tough standards on asbestos or radon daughters, but if we are going to have tough standards on those we have to see those standards in relationshop to the risks that we also accept for ourselves in our technological society. So it continues to be a puzzle to me. In a kind of seminar way, Mr. Chairman, I would be interested to ask Mr. Mackenzie this basic question: How do you decide what an acceptable level, for example, of asbestos is?

Mr. Mackenzie: I do not have too much trouble with that. My observation has been that the standards that we have set, and you are always in danger when you set tough standards, have never been anywhere near as tough as one might get--and I am talking about involuntary risks now--or one might feel, as you believe they are. I do not think we have come anywhere near to being tough enough in terms of the kind of standards that we are going to set. Those standards have got to be pretty broad if we are going to deal with some of these problems.

I would have no problem in toughening up the procedures in terms of nonsmoking areas and a lot of other things to do with smoking as well. But I have not yet seen a standard set that I consider, in the industrial work place, anywhere near tough enough. It is not an argument that you will get from most of the companies, but it certainly is one that has been my observation any time I was organizing or working with the trade union movement. So I think we have to consider tougher standards right across the board in terms of worker health and protection.

Dr. Ham: All I plead with--and I do not for one moment disagree with you; obviously, this is your view and it is proper--all I plead with us is that when we say, "Okay, we want this standard to be tougher or that one looser," we address that question not as an isolated question but in the context of the whole pattern of risks that surround a person working and living in our society.

Mr. Mackenzie: The difficulty with that, and I listened to your remarks on that as well, Dr. Ham, is that it is pretty hard to use a broad brush on terms of what is wrong with society. What I found usually happens is you have to zero in on an area where you have a problem. God help us, we should have zeroed in a long time ago at the Johns-Manville situation here in Toronto where almost half the entire work force is now either on pension or has a pre-asbestotic condition. The extent of the damage there is just unbelievable. I am sure we knew of it earlier but it has only really surfaced maybe in the last 10 to 12 years.

My concern is that only when we have been able to zero in, only when we finally had some real problems in the mines and your commission resulted, did we start getting the kinds of changes that are in their infancy as I see it right now, and this concerns me. I am wondering if it is your feeling that we really know what we have done, or haven't done it is hoped, in terms of toxic substances or exposure for miners, in the uranium mines in particular, because it is only, what, a 30-year industry.

Dr. Ham: I just don't know. This is really not much help to you. I just have the tremendous sense that we are wrestling with a very complex human issue. There are people who argue that the excess lung cancer in the mines is not due to radiation, that it is due to something else. When we have situations like this, there is no damned excuse for not spending the money to do epidemiological studies and so on that are necessary at least to try to identify these things, and in that sense we have been very shoddy and lacking. We haven't kept adequate records on people. There are all kinds of facets of this which--

Mr. Mackenzie: I suspect there is a hell of a lot more to do with dust and the materials that would be in the dust than radiation alone.

One final question: One of the things that I think bothered us all--I am sure it did, regardless of the positions we took on it--was the uncertainty in terms of the final disposal, I guess, of the tailings site. It is not a pretty sight, some of the areas you see around the uranium mines. I am of mixed emotions myself. I suspect the attempts at vegetation over the top of some of the tailings is probably one of the answers, but the period that has to be looked at is so long that it really concerns me. It is not a scene that could make anybody who has taken a look at the tailings happy. I am really wondering if there are any comments, or whether your commission really got into the question of the tailings at all.

Dr. Ham: We paid no attention at all to environmental conditions outside the plants and therefore gave no attention whatsoever to tailings ponds. There is a kind of peculiarity, but if you are inside a plant, then you want to get all the toxic stuff away from the work place, and if you want to get it away from the work place one natural place is to vent it--it either goes out in waste streams or out a stack and so on--so there is a kind of interactive problem here. Our concern was with the occurrence of toxic substances sort of inside the enclosure of the plant or the mine, so I am able to give you no instructive comment whatsoever about tailings ponds. I realize it is part of the whole system.

Mr. Bounsall: In your remarks, Dr. Ham, you mentioned susceptibilities and susceptibility of workers to back injuries or fume susceptibility. As you mentioned, you had at least an awareness of an irritation of the sulphur oxides and so on. In your commission report at that time, did you find that there was prescreening of workers in the mining industry for those who might be hazardous with respect to themselves? Did you detect any of that at that time?

Dr. Ham: No. I am aware that most companies give their employees medical examinations of some type and, of course, as I recall, under law in the mines there is particularly the requirement to verify the status of lungs, the respiratory system. We did not interview or discuss with mine management, other than in an informal way, the procedures they may or may not follow to select workers on the basis of medical evidence of susceptibility.

I can't verify this for sure but I would suppose that when mines hire people to work underground there is a certain physical robustness about such people; that seems to be perfectly natural. I was trying to raise what I think is really a difficult problem and that is to what extent should there be public understanding or legal requirement or otherwise for such examinations to take place and then what do you do if indeed you detect susceptibility?

11:20 a.m.

If you detect susceptibility in a worker should special efforts be made to ensure that person of a work place where the occurrence of irritation will be minimized or does that person sort of take his luck with everybody else knowing that he is susceptible? Does he sign a form saying, "I accept this employment knowing that you have informed me that I am susceptible"? I just toss this out as a complication on the issue and I do not know what the answer is.

In terms of high-risk employment I suppose it is possible that we could have a system of hazard pay and informed consent, that sort of thing, which is an entirely different approach to it from what most of us would prefer to take socially.

Mr. Bounsall: One could always have a bonus system for safety, bearing in mind the evidence we have of smoking adding quite materially to lung problems whether they arise from dust or radiation--a bonus system for someone who stops smoking, prescreening and perhaps picking only those who up to this point haven't, and so on; perhaps that would be acceptable.

One other closely related area that you mentioned in your recommendations is that you said the Elliot Lake miners exhibiting dust effects should be eligible for a work adjustment program. This touches on one of your last remarks there. When you find the susceptibility, what is the responsibility to see that that irritation or risk is minimized? You did make that recommendation with respect to the lung dust effect. I would assume that you are touching on rather more extension of that. If you see someone who is susceptible to fumes, even if it is only on an irritation basis, that should apply in that regard as well.

Dr. Ham: Right, I agree that on the issue of taking someone out of dust or radiation or irritation I do not think we have resolved how we properly respond to these circumstances.

Mr. Bounsall: But that is what you are saying to us is one of the social responsibilities we should look at.

Dr. Ham: Yes, if you know that people are susceptible; some people are more susceptible to injury than others. I guess I am raising the question, what do we do about it and what is socially decent and compassionate and wise in responding?

Mr. Bounsall: Further in your recommendations you said that those workers subject to exceptional exposure to environmental hazards should have an automatic entitlement to rehabilitative compensation from the Workmen's Compensation Board. Were you thinking of the miners or mill workers at Elliot Lake, where they get the silicosis dust and the radiation hazards and the radiation particles attached to the dust, as being a group of workers who are subject to the exceptional exposures?

Dr. Ham: Could you acquaint me with which particular part that refers to?

Mr. Bounsall: Recommendation 22: "That the Workmen's Compensation Act be amended to provide clear entitlement for rehabilitative compensation based on the principle of work adjustment for persons subject to exceptional exposure to environmental hazards." Did you have the Elliot Lake miner or mill worker in mind?

Dr. Ham: Mr. Chairman, this was a recommendation in principle, because my understanding was that the Workmen's Compensation Act is framed in such a way that before the Workmen's Compensation Board can make compensation, there has to be demonstrated injury. This was a proposal to extend the basis of the Workmen's Compensation Act in principle to allow it at least to spend public funds in a rehabilitative way on the basis of work exposure without the necessity for the demonstration of substantive injury.

Mr. Kerrio: Excuse me, Dr. Ham, that would not necessarily be public funds.

Dr. Ham: Forgive me for saying that. I mean the Workmen's Compensation Board. I realize it is funded primarily on the basis of--that's a mistake. I apologize.

Mr. Kerrio: Thank you.

Dr. Ham: It's an issue of principle and I am not sure that the board feels that it now possesses that right but it was consciously directed to at least extending the legal right of the board to expend the funds under its charge to assist in rehabilitation without there having to be a priori, substantive evidence of actual injury.

Mr. Bounsall: And by injury, I assume you are including the health hazard section of it. By injury, one often thinks of the loss of a limb or the loss of a finger. You are meaning the general health effects, lung effects and so on when you say injury.

Dr. Ham: Mr. Chairman, by whatever judgements the medical profession is able to impute injury of any form.

Mr. Bounsall: You went on and recommended further--and I presume you are still of the opinion--that they should receive that rehabilitation compensation for a reasonable period which you state as two years, as well as moving, travelling expenses, relocation expenses and counselling beyond what they would normally get from the Compensation Board to deal with their relocation and to make them aware of the health hazard problem to which they have been exposed.

Dr. Ham: I can't recall all the details, Mr. Chairman. It was the issue of principle that I was concerned with there.

Mr. Chairman: A supplementary: I am curious about the hesitancy to have prescreening of workers who are going into a hazardous industry such as mining when I reflect, for example, that there is pretty rigid prescreening of all susceptibility and health conditions to get into the armed services. We heard appalling assessments of the health standards of the Canadian people during the war because of the number of people who were turned down. Well, if war is hazardous and you therefore turn people down, why wouldn't there be a fairly automatic acceptance of prescreening as a legitimate approach in a hazardous industry like mining?

Dr. Ham: Mr. Chairman, I am not suggesting there isn't. I was just, like you are, saying this is something we ought to face. It's one of the things we ought to face up to because one of the things you can determine, reasonably in some measure, is the difference between human beings and we shouldn't neglect those things.

11:30 a.m.

Mr. Williams: Dr. Ham, I just want to share with you for a few moments some observations I made on the trip to Elliot Lake out of which there will be some questions. I personally found the visit most informative to the committee individually and collectively. A number of the things that you touched on this morning were quite evident in what we saw during our visit. In particular, you touched on the matter of corporate responsibility as being a very important ingredient in the whole process. You talked about susceptibility and informed consent and openness between the workers and the employers.

I found, and I must say I was impressed by the fact that there were four sectors of the community actively concerned and involved in this whole matter within the community in Elliot Lake. I think it was self-evident from the fact that on our tour through the mines, not only were we escorted through the mines by our host, the companies, but also present were members from the various ministries of the government--labour and the environment--and there were senior representatives present from the unions, as well.

I think that has something to say in itself, that all people were involved, and most importantly, that there would be representatives from the unions participating in the tour. The members of the committee had an opportunity to question, at length and without restriction, company representatives, union representatives, people who were there from the Ministry of Labour, those who had come in from the Sault and Sudbury from the Ministry of the Environment. They all participated and gave the members of the committee full opportunity to raise many of these questions and get many answers to them.

I felt that is simply illustrative of the points you made earlier this morning, where you felt that anyone going into the work place, while there is an involuntary need to work, there is the voluntary aspect of choosing your place of employment; and in order to choose wisely,one has to be informed. There has to be openness between the management and the employees so the employee knows what he or she is getting into.

I must say, based on the involvement of all of these people, having visited the training schools that Denison Mines operates in any event, and I think Rio Algom do in their own way, as well, bearing in mind the new legislation which involves company-union negotiations at all times about safety in the work place, and having heard at the end of our trip a presentation from Dr. Smythe from the Elliot Lake centre, showing that there was also a very heavy and active commitment of the community at large involved in this concern for the safety and wellbeing of the workers in Elliot Lake, I felt there was a very good co-ordinated effort going on in these four sectors. I suggest it is not in spite of, but perhaps because of your report that this positive working environment and co-ordinated effort between all these parties has emerged largely out of your report.

I gathered from your earlier comments, however, that you have not had occasion, personally, to return to Elliot Lake and to review the situation since how you saw it back in 1976. Is that correct?

Dr. Ham: That is right. I haven't been in the Elliot Lake mines since 1975-76.

Mr. Williams: You have had no opportunity to measure your findings from your personal visitations and involvement with all of these people between then and now, to gauge the degree of progress that appears to have been made. Based on comments that were made to us at the public meeting held on the Wednesday evening, the union representatives indicated they weren't happy that progress was taking place as fast as they would like to see, but acknowledged that a great deal of progress had been made.

I think the members of the committee were very impressed with the efforts made by the companies to develop new technology in the areas of the dosimeters that the workers will be wearing in the immediate future and in other areas such as this. All of these experiences seem to indicate a co-ordinated effort by the whole community which I think impressed all of the members of the committee.

I did want to try to determine from you whether or not you were able to make any of these comparisons. I gather you are not able to assist us in that regard at this time.

Dr. Ham: No, I am not, Mr. Chairman. I indicated my own view of the privileges of a person who is a commissioner. As you well know, when one is conducting a commission, as in some sense you are, you have the privilege of probing into other people's business in a singular way, examining these and making recommendations. My own view was that once I did that I should simply not take one's self so seriously so as to pretend to be a monitor of the responsiveness of any parties to this. So I have not made a point, if you like, snooping about to find out what has happened.

That does not suggest that I do not have a keen personal interest in these issues. What I have done in recent years is to discuss, in some sense, the philosophical aspects of these things because, as I have tried to indicate this morning, we are dealing with what is really an immensely complex human issue for which there are no simple answers. In the end, we have to declare socially, what we insist will be the guides within which we then function socially. In the discussion this morning, there have been concerns about standards. I am all for us having tough standards, provided we understand the implications of having those tough standards, not only in terms of human lives, but the whole activity of working.

There are really three aspects of this, perhaps. There are standards which are really objectives that we legally wish to achieve in terms of exposure to toxic substances, and so on. There is the sort of quality in the way we work together. This is what I understand Mr. Williams to be referring to, that he has some sense of satisfaction in his observations over community, union, worker-management relationships in uranium mines. That is absolutely essential. If there is not some good quality of continuing to wrestle with the puzzles, then standards will not achieve what they set out to do.

The third facet of it is your own work and that of the Legislature and the ministries in establishing this framework within which this all goes on. There are many defects in this system. We are a long way from having proper occupational health records.

Let me give you an example of an area which is another conundrum: noise. I think the record of the mining industry with respect to the damage of hearing of workers is abominable. There has been a lot of improvement in these things in recent years. It is not just the record of the mining industry that is abominable, the record of any noisy industry is abominable. You think historically of weavers and boilermakers. Going deaf was socially accepted in the sense that people chose to work there. They went deaf relatively early in their career. They were weavers, they were boilermakers and they were miners. We are obviously much more alert to the issue of noise and its influence on us, but there are conundrums about that. I do not hesitate to remind you of the conundrums.

11:40 a.m.

One of the directors of one of the large companies that I visited, and I was not in the mining industry at that time, suggested to me--and I would not want to be held to this statistic--that something like one in five of young people these days have significant hearing loss in their early 20s which some people impute to the use of so-called hi-fi. We live in a social situation where we are really cleaning up our act, socially, with miners and people like that.

At the same time, on the lifestyle side we have our sons and daughters, and perhaps ourselves, who proceed on a lifestyle basis to impose on ourselves injuries which are utterly absurd. That simply is another illustration of the fact that when we talk about standards and talk about risks I think, if I may say—and this is impertinent of me--it is the duty of a group such as yours to remind us who are citizens that the issue of voluntarily imposed risk is a tremendously socially important thing that cannot be neglected.

Mr. Williams: Dr. Ham, you said you were going to quote to us, and you did, what you characterized as being a provocative statement by a leading British authority on the subject of cancer. What I thought you were going to say and what you did say are two different things. He concluded that the adverse effects of the work place were minuscule compared to the injuries we do to ourselves voluntarily in society by our own chosen lifestyles.

Dr. Ham: I think he was saying that.

Mr. Williams: Yes, that's what I gathered from it as well. I found that quite provocative. I guess I can use that term. But I guess that statement was really borne out from our experience in Elliot Lake. I mentioned earlier our last day there and the presentation we had from the Elliot Lake centre, Dr. Smythe's group.

They are making great advances in this area of sputum cytology. I think they impressed the committee with the fact that their centre will perhaps be the leading centre in the world for this type of research. What I found startling was the fact that such a high preponderance of the number of workers who have volunteered in this program of sputum cytology who were found to have contracted a form of lung cancer were workers who had a smoking experience. Virtually all of them were at that time, or had been, smokers. I think it was over 80 per cent of those who they found had contracted lung cancer and who were suspected because of dust inhalation in the work place who had this one common characteristic, namely, that they were smokers.

That became quite evident in the information that was provided to us, and I suppose that reinforces the argument the British authority was making on that particular point. Do you have any observations or comments on that particular point?

Dr. Ham: I think this brings the question back to one of the themes I've tried to leave you unsettled about--the dilemma of the voluntary versus the involuntary. I suppose one of the regulations one could make in the mining industry is that you may not smoke if you mine. But is that a socially agreeable kind of rule to have, that you may not work underground in a uranium mine if you smoke?

Mr. Chairman: You may not drive a car if you don't wear a seatbelt.

Dr. Ham: It raises the whole puzzle of what you regulate. I'm not a medical person. I accept what has been commonly stated, that one's risks of cancer as a uranium worker are much higher if one smokes than if one does not smoke. That's a perfect example of where you juxtapose the freedom to decide how you live with the puzzle of what happens to you when you work in a mine.

Mr. Williams: I think it just speaks to that point the authority was making.

Dr. Ham: Lest I convey any notion of a kind of sense of unconcern about this, just because one smokes is no damn excuse for accepting unreasonable excess lung cancer in a uranium mine. In other words, I think you sometimes tend to say that so much damage is done by smoking that we can neglect these industrial things; they are not important. I am not saying they are not important, I am just saying let us realize the interaction of these things and when we do decide what our standards are, we do it in the context of those things.

It does not matter how large involuntary risks are. That is no excuse for accepting involuntary risks of the work place if they can be reasonably disposed of. I guess if I have any conviction, it is an absolute responsibility for every management and every engineer who designs technologies to see that the human risks that can be reasonably disposed of in design and operation ought to be.

Then you get down to the question of what you mean by "reasonably disposed of" and "best practicable means" and so on. Those are not easy questions, but it ought to be a kind of overriding demand on engineers, designers and operators that risks that can be disposed of are disposed of.

Mr. Williams: I do not think you will get any argument on that score.

Mr. Fisher: Dr. Ham, I wonder if we can extend this concept of voluntary-involuntary risk through the action of the workers in the work place, that there are certain risks that are inherent in mining some of which are involuntary in the sense that if a worker works underground he is the recipient of whatever ventilation system has been supplied by the mine. He is the recipient of whatever equipment he has been given. On the other side, he has certain voluntary risks and he can choose to do a good job of securing his work place before he drills.

Would it be fair to take the Chauncey Starr proposition and extend it to the work place and suggest that workers are going to insist on a higher standard of involuntary risk from those things which the company can do for them than they will impose upon themselves?

Dr. Ham: That is a provocative question. As I worked with the people who supported me so ably, I learned to think about that particular one in terms of the definition of unsafe conditions and unsafe work practices. You try to divide the work place up into those things which, in a sense, are not the workers' responsibility, but they are the conditions of work, and then the question of the way in which the worker conducts his work.

I do not like that dichotomy, but I think you raise it in a particularly interesting way. Let me just repeat what you said. You said that it may be characteristic that workers--and let us enlarge it to society--expect a higher standard, that is, lower involuntary risks as imposed by a company or a society, such as in the water system, than the worker or participant in that situation will impose on himself.

Mr. Fisher: Yes.

Dr. Ham: I am prepared to accept that some workers work more carefully than others. Some people drive their cars more carefully than others. I think you are pointing to a potential human situation where the issue of voluntary-involuntary rears it head, so to speak, and presents itself in the very active work. I think you raise an interesting question, but one has to be aware of then using it.

I have heard industrial people say, to use a particularly provocative form, that almost all accidents in work occur because of unsafe acts. Basically, accidents are the fault of the worker because he does something that isn't in accordance with procedure, or he uses a tool in a way that it shouldn't have been used, or he just does something that is unsafe, over or against the business of unsafe conditions.

11:50 a.m.

I think that is a damnable kind of point of view to take. On the other hand, there is intrinsic, it seems to me, in the act of work the consciousness that I am an individual and I can do things my way versus the fact that I am an employee and I work in a certain place and am supported or interfered with by my supervisor and everything else. I can't illuminate that problem other than saying I think there is an element of possibility there, but be very careful not to project that to the point where you start to argue and use the thousand to one sort of ratio of actual responsibility. But it is a good point.

Mr. Fisher: I just wanted to do that as a start and then ask you a little bit about the two sides of it, the involuntary and the voluntary part of work underground. I know you made the point that some industries are innately riskier than others and maybe we have to accept some of those things. Is it unreasonable for a committee such as this to take the approach in terms of radiation risk that we should be able to look across the nuclear industry and say that if five rem per 12-month running period or three rem per quarter is a maximum permissible dose in one side, then we should be looking for a similar kind of a standard, a similar risk, although we know the number will be different, the unit will be different, in the mining industry or in the fluorescent light business or whoever else uses radiation?

Dr. Ham: Is Mr. Fisher talking about sort of typical average exposures or legal regulations?

Mr. Fisher: I am looking for legal regulation at the moment.

Dr. Ham: May I ask a question, Mr. Chairman? Isn't the same radiation standard applicable to workers around reactors as is applicable to workers in mines, the same legal regulations?

Mr. Fisher: I believe they are, except we are looking at the beta gamma radiation essentially around for workers in plants, and we are looking at five rem maximum, although it is a standard which combines various kinds of radiation. We have a different kind of radiation in a mine, which leads us to the working level idea.

Dr. Ham: I am not able to interpret all the biological effectiveness of these things, but my sense is that at least the intent of regulation is that workers in mines shall not be exposed to more intensity--this is a legal limit--than workers around reactors.

One of the things that really shook me up when I did this study five years ago was to observe--and I state to you that I think it is an interesting human question--why, in God's name, have we been so meticulous about workers around reactors and so historically negligent of workers in mines? Is it because the human beings who work around reactors are more valuable than the human beings who work in mines? I hope to God that is not true.

We have real puzzles. We spend millions and millions of dollars to ensure that radiation exposures, actual exposures of workers around reactors, are negligible--this is on a relative scale--with respect to the exposures that workers in mines incur. Why? I won't attempt to answer the question, and I am not sure I know an answer.

Mr. Cureatz: Excuse me, but don't you think that one of the possible considerations is if there is any feasibility of any kind of extreme radioactive exposure to a worker, therefore the next step is extreme radioactive exposure to a large surrounding population? I suppose the attempt is if we can limit it to nil to the worker, therefore--and I don't know but it's the first thing that came to my mind.

Dr. Ham: I won't agree with you but nevertheless in human terms, it's an interesting question. Look, I will be frank, I will be blunt. I think socio-historically we have valued some workers in some sense more than others but I think this poses us problems.

Mr. Kerrio: Also, physically you are building one structure and you are trying to wrest from the bowels of the earth the other.

Dr. Ham: It bothered me when I did the commission to realize what absolute meticulous concern was being taken for workers around reactors and in some sense there was a less meticulous concern for exposure of miners.

Mr. Fisher: It's interesting you raise this analogy because that was just what I was going to ask you next. Let me try the following proposition on you. We do have, and I think this committee saw, the meticulous attention that was paid to safety and to engineering in high levels of safety in the reactor side of the nuclear business, but what you also saw in there was an industry whose economics depend upon a high level of reliability of equipment: Keep the equipment running smoothly without interruption for a long period of time--it is an approach which is conducive to having a safe environment--and reduce tritium releases because it means you are leaking heavy water which is very expensive and at the same time you are protecting the workers. Then the two start to go hand in hand after a while so that you start then taking the same approach to safety as you took to your equipment.

One of the things that struck me from the trip into Elliot Lake is that we have in the mining industry what I would call a rough and ready kind of business. There's a sort of a toughness to it. The job is moving tons of material. The workers have the feeling, the companies have the feeling. Everyone wants to do tons. When we went on the trip through the mill, the mill had stopped for a while because someone had loaded some great big rock on to the thing that he wasn't supposed to and we asked the mill worker, "Does this happen very often?" He said, "Oh yes. It happens every so often." I said, "I thought you couldn't do that. They have got all these grates." He said, "Tons is what they are after down there and they will find a way to give us a big rock if they can." That's the sort of general approach to it.

So you have really a different approach to the whole industry. In your report you put a very high reliance on the development of the right kind of climate between workers and management of working together to do something. It struck me that when you have an industry like the hard-rock mining industry we are placing reliance on an area where we are not going to get a lot of results and that in fact this is an industry that will require, if we want to raise the standard of safety, more regulation; you really have to fall back on regulation rather than hope to build a different attitude towards safety.

Dr. Ham: If I can philosophize on this for a minute, in the University of Toronto we are a licensee under the Atomic Energy Control Board and we have 300 laboratories in which radioactive isotopes are used. Indeed if you read the press back in May there was a wonderful story about somebody eating radioactive material in his Coffee Mate. The allegations of not having pursued this were all wet but there was a problem. Anyway, recently the Atomic Energy Control Board has said that it would withdraw our licence if we didn't guarantee more effectively that all the laboratory doors were locked when people weren't there. I am revealing institutional problems but there have been incidents in these 300 laboratories where somebody would come along perhaps in the middle of the night and find a laboratory that had not been locked.

12 noon

We had two alternatives on how to solve this problem to the satisfaction of the Atomic Energy Control Board. We could install electronic surveyance on all door locks--that would cost about a quarter of a million dollars--and we would have a central computer scanning all these locks saying, "Are they closed? Are they closed? Are they closed?" and you would get a printout, over against some system of local responsibility that has some kind of bite and sanction in it.

What we have resolved to do is that if somebody leaves his door unlocked more than a couple of times he is going to have his right to conduct research removed. That will, of course, create ructions if it happens. But this is the question of trying to get local responsibility. Regulation is socially necessary but I think one of the great dangers in our society is that we will believe that regulation will, in itself, resolve the problem that we are trying to solve.

In the university situation I was all against the kind of master surveyance where I suppose in a mine you might set up television cameras in every stope and drift and have somebody watching these damned things. I do not think that is the way to really ultimately deal with the human situation. One has to have some kind of hard-rock regulation on standards that really inform us about what does insult the human being, what injures.

So you say that because of its nature the mining industry requires more regulation than what else? I am sceptical about the effectiveness in the end of simply elaboration of regulation as a means of actually achieving a desirably social result. I am all for regulation that puts in legal form our collective knowledge of what hurts people and under what circumstances, which contains a social judgement of how much of that hurt is necessary for a productive economy and acceptable in terms of risk. But if you go on and try to use regulation to resolve what are basically long-term issues of the capability of people to work together, to supervise one another, to design equipment and all the rest of it, to do good engineering, to do good design management, I think we are spoofing ourselves.

In terms of our kind of society I think that it is terribly important to keep emphasizing the central importance of the quality of the human working relationships around which you building certain regulatory fences. But I think one of the terrible dangers of our increasingly complex technological society is that we will in fact over-regulate ourselves and not put enough emphasis on the humane issues that are at the centre of these questions.

Mr. Haggerty: If I could ask Dr. Ham one question. A question was asked before related to the right of workers to refuse to work in unsafe places or conditions in the industry. In your recommendation 60 you have in rather strong terms that "statutory provision be made for the appointment at each mine and plant of worker auditors having the authority and responsibility to examine and report upon conditions of workers pertaining to the health and safety of workers at sets of work places designated by management." That is a pretty strong recommendation by saying "statutory." Could you give us the reasons for that strong recommendation? That will be chapter four, Accidents and Injuries. It will be recommendation 60 on page 269.

Dr. Ham: "Statutory provision be made for the appointment at each mine...of worker auditors..."

We had been in England and looked at worker representatives in the coal mines. We had been in Sweden and gone around mines with worker representatives in Swedish mines. At that point, I was reflecting the point of view that workers should have a right to contribute an appreciation of the general quality of the working environment. I believe that.

Suitably qualified workers should have the right to contribute their appreciation to management of the circumstances that surround the area in which they work, particularly in mines because, as someone said, it is one of these places where you are changing the face of the earth to take things out of it. It is complex and is intrinsically dangerous. That was a conscious, clear sense that there should be a right of suitably qualified workers to contribute their appreciation of the risks and circumstances, the good things and bad things that are involved in working.

Mr. Mackenzie: One of the things that surprised me a bit was the efficiency level of the equipment that they are using to monitor air samples and so on in the mines. I think at Denison the monitors there told us the efficiency rate--and they gave you a picture of it--was very low in the equipment that they had. Do you see the need for developing better equipment as one of the problems?

Dr. Ham: I am no expert on monitoring equipment, but our technical capacities in this regard in the last decade are so amazingly higher than they were that I would suppose, without having any working practical knowledge of ranges of whose equipment is available, that these kinds of problems should be--

Mr. Chairman: I think it was not the efficiency of the equipment it was the efficiency of the procedure of sampling. If you take one sample of air in a certain area of the mine, for example--

Mr. Mackenzie: A personal dosimeter might resolve some of that but what they did have, it struck me, could be more efficient.

Mr. Chairman: Coming back to Dr. Ham's earlier comment that he was struck at the different standards in terms of safety in the mines as composed with the generating, I have come to a tentative conclusion that the use of personal dosimeters is the only way in which you are going to be able to get the accumulative effect of radiation. I share your puzzlement as to why that has become so imperative in the generation and is only now being considered in the mining.

Dr. Ham: We should be capable of measuring damned near anything these days. But, as I say, I am no help on that.

If the questions are complete, Mr. Chairman, I would like to raise one question with you. It goes back to regulations, and it relates to what Mr. Mackenzie, Mr. Fisher and others have said. It is this business of sanctions. Why do we have regulations? We have regulations to inform ourselves of what ought to be, based on physical human understanding. But regulations also impose sanctions. The significance of regulations, apart from all the red tape they create, is that there is the implication of sanctions.

I have said, and I believe this fundamentally, that in the university situation, for example, it is better to impose a sanction situation where we close down a laboratory than it is to enter into some monumental technological surveillance system which relieves from the people at the local level the responsibility to be doing the things that they ought to be doing anyway. So one of the puzzles, it seems to me, in management-worker relationships these days is the question of to what extent can either bonuses--someone suggested that bonuses might be provided for people who worked safely; that is one side of it--or sanctions for people who do not work safely be effective.

12:10 p.m.

So how do you, in a nonregulatory way, impose some sense of discipline which can be facilitated either by bonuses or sanctions in the worker-management-supervisor relationship? I don't know, but I suspect, and here I may be provocative, and I know this in my organization, that we live in times when we tend not to want to impose sanctions on one another, that the issue of discipline in management-worker relationships, personnel relationships, is very difficult. We tend to be building a society in which we have all kinds of regulations, but we are not willing to place directly the issue of a sanction in a manager-supervisor-worker relationship, or an interworker relationship. I don't know what the answer is, but I think we are tending to build a society in which we want to rely more and more on a framework of regulations which are sort of out there, leaving maximum freedom either in a life style basis or on a work performance basis.

There was a time which I guess was brutal and unreasonable, when the so-called shift boss in a mine could fire a man sort of on the spur of the moment if he performed in some way that was unsatisfactory. We are a long way from that, but I guess I have the sense that we are going so far away from that that the question of the exercise of either incentive or sanction in the immediate working situation is now tending to be so limited that we tend to place more reliance to deal with the sort of human problem in formal regulations. I guess I just re-emphasize I think that is dangerous.

Mr. Kerrio: Dr. Ham, that was the area I was going to delve into. The reason was I had a comparison written down here where the civil courts have addressed themselves to such a responsibility, where in a civil action where they have handed down a substantial sum of money to an individual who was involved in an automobile accident, if you will, the injured person had his allotment reduced by a substantial amount because he didn't have his seatbelt fastened.

In a sense, this is the type of comparison you are making, and it was one that I wanted to enter into, because I feel that unless some of the responsibility is shared we won't have a work force and a company and a government that are going to be in the game together, that if we transfer all the burden on one side and we do it with compensation, it is one of the very few areas in our society where there is no assessment of fault, and it is so easy then to transfer it.

Those people on the socialist benches who think I am against workmen's compensation, of course, are wrong, because I am not. All I am suggesting is that there should be a more participatory action on the part of other parties if fault can't be laid to the particular individual. Right now that is not true, and it is very easy to participate in sort of an involvement where you transfer all the responsibility to one particular area.

I just wonder, if we don't change that a bit, if we don't get people to assume personal responsibility, if we are ever going to go any further after we get to a point where the work place is what we consider safe by standards that maybe are international, if you will.

Another question I was going to raise with you, and I suppose it is what you have been telling us here, is that there are those who would suggest that after we are convinced we have got the work place as safe as we can possibly make it, we then have the broader question of saying do we continue nuclear generation or do we take into account those people who say it is much more dangerous to the worker, to the environment, to our whole being to go burning coal in a thermal way and spread it much wider and maybe increase the accidents in the mine because of such a greater amount of tonnage to be mined?
That is the larger question, I suppose. It goes beyond what you have done for us to assess this, and I accept that responsibiity.

I would only ask you one more question. Have you gone to other jurisdictions and compared them to our operations in Ontario as related to mining? How would you compare other jurisdictions with what we do?

Dr. Ham: In the course of the commission, different members went to different places. When a person probes on this basis, it's very difficult to judge how capable he is socially in dealing with these issues. I guess my sense is that in Canada, and not least in Ontario, we're wrestling with these things as sensibly as most jurisdictions we would think of comparing ourselves with. I'm just not able or competent to give any judgement of the effectiveness of ministries or civil bureaucracies.

Mr. Fisher: I had a supplementary on regulations.Why have them? One reason is there is an implication of sanction which you can attach to it. But it seems to me the other thing you're achieving is that you are establishing some rules that everyone then can work towards. Engineering will work towards those kinds of rules. If you establish a rule that says you must drill before you bolt, somebody is going to come along and the machine he sells you to do rockbolting will make the drilling happen before you can get in and bolt, if that happens to be a good way of doing it.

When I've been looking through these files of accidents which have happened up there, what strikes one over and over again is, first of all, it's an unsafe practice. Someone did something he shouldn't have done. Secondly, over and over again you see it would have been easy to engineer it so it was impossible for someone to do that. You can assume he's going to take a shortcut at some point. If so many thousand workers are working in a mine, a certain percentage of them are going to be taking shortcuts every day.

If you had some rules established saying that that's the way it's going to be done, people would start to engineer equipment so that people couldn't take those shortcuts. Maybe you need regulations, maybe you need setdown rules that everyone knows, from the guy designing the equipment to the person who's in there working, in order to have that happen.

Dr. Ham: If it's a question of the design of a piece of equipment--I just offer these observations--it seems to me you can encourage the evolution of the design of machines. Look at Three Mile Island. The latest thing I've read--and I commend it to you--is a review article by the head of the commission.

One of the things he pointed out was that the design of the control room was just disastrous for purposes of allowing human beings to respond properly to this particular emergency. One of the things that was wrong at Three Mile Island was that the human factor design of the control room was just very poor.

It seems to me you could encourage better technical design and, God only knows, as a person with an engineering background I believe that's dreadfully important. You can encourage it two ways. One is you can write detailed specifications and regulations and in terms of customers asking for something, obviously that's entirely legitimate. The other way is to create a kind of general social sense of the significance of these things.

My own personal judgement is that in engineering there hasn't been enough innate social sensitivity to this. It hasn't existed in engineering education. There are two ways to get at this business. One is to raise the general sense of what I would call civil literacy about things, that, damn it, it's important to design equipment to work safely.

People will say "we do that", but there are too many blatant instances where equipment just isn't designed adequately. There are two sides to it. One is to write regulations and the other is to intensify a kind of general social sense that these things are important.

What I detect is happening--my own work was just a small part of this and the fact that you're here is another illustration of it--is we are becoming socially more sensitive to this. We have to become socially and civically more literate.

I think civic literacy, a general understanding among labouring people, all of us, in the long run is more important than the actual regulations. The regulations are the outcome of these things. I am not against regulation but I am against the view that regulation in itself will create the kind of balance of human involvement and fruitfulness that we are seeking.

12:20 p.m.

Mr. Chairman: Perhaps I can emphasize Mr.Fisher's point because there is one aspect of it that, at least in my perception of it, I do not think you address. The point he was making was that the economics of generating nuclear power are such that it is good economically to be safe because if it is not safe, if it is not well engineered and the plant is going to drop down, you are not going to have a reliable system. If there is a tritium release that is because you are losing heavy water. Economically there is an incentive.

As I perceive it, the reverse is the case in the mine because the economics are to produce more and to cut corners--and everybody conceded that there were corners being cut--to produce more. How are you going to counter that basic economic thrust at the mining end if not by regulation?

For example, we were told--and maybe it is fortuitous--that if you examine the statistics on accidents that the accident rate is much higher in boom times when they are really trying to produce as much as possible. We had it argued to us by the steelworkers in their presentation that the bonus system, which is designed to add to production, has never had built into it a safety component. So how are you going to counter the basic thrust at the mining end for more production if you do not have a regulation, other than by the bonus system, which is one way, if you bonus safety.

Dr. Ham: Mr. Chairman, I am last person to give you a wise response to that question. I guess the problem exists, as you put it, for more for than the mining industry. Foresty is statistically more dangerous than mining. I do not know if we have good statistics on farming but my sense is that there are a lot of accidents in farming. I suppose it is endemic to human affairs that wherever the issue is productivity in some sense, this issue comes up. Without knowing, I would not want to give any special black marks to the mining industry. I would suppose that this exists in particular in the logging industry and in some facets of farming.

Mr. Chairman: You are right on the farming. One of the reasons why most farmers have not gone into compensation is that the accident rate is so high that the payments are prohibitive.

Dr. Ham: Obviously, we need regulation. I guess the point I am trying to make is that regulation in itself will not resolve the issue. Associated with the regulation there has to be a kind of social understanding of the whole balance of risks. I think it was Mr. Kerrio who said that if you are going to address the question of should we have nuclear energy or not, you cannot address that as an isolated question. You have to ask what would you do if you do not have nuclear energy; and that is obvious. Then when you do that you begin to think of nuclear risk in context. I am not arguing against regulation, I am arguing against the faith that regulation alone will cause the consequences that the regulations are intended for to come about.

Personally, these days I guess I would be more wrought up if we have a good regulation that is disobeyed than if in some sense we do not have an extra regulation because this question of what transpires between writing regulations and then what actually is manifested in human behaviour is a tremendously important thing . I continue to believe that it does not matter how many regulations you have. Management-labour relations set the community understanding of what an industry is. These things are absolutely fundamental and the regulations are obviously necessary guidelines.

Mr. Williams: On a point of clarification if I might, Mr. Chairman. You said that we all agreed that it had been conceded that corners were being cut to produce more. Could you just refresh our memory as to who made those statements and in what contexts, Mr. Chairman?

Mr. Chairman: I have forgotten exactly who said it but if your bonus system is to produce more, it was conceded I think by somebody that every day corners would likely be cut to increase the production.

Mr. Kerrio: One comment, it's important that the money generated by the extra production pays the bonus and that has never been said here. The extra money that's brought in by the company for the extra production goes to pay the bonus and I mean you have to keep that in the context. That's what it's all about. It pays the worker.

Mr. Chairman: Does that satisfy you? I can't give you the exact author.

Mr. Williams: It sounded more authoritative than the way you put it to me, Mr. Chairman. I certainly don't remember any authoritative statement being made on that subject and I think it implied that there were--

Mr. Chairman: If it came from the union, it wouldn't be authoritative--

Mr. Williams: --safety corners being cut and I don't think that was the case at all.

Mr. Chairman: Bob, did you have a question?

Mr. Mackenzie: I am interested because it's an area that I have been concerned with, this discussion we have been having underlying everything here today over the standards or regulations. I am not sure that to some extent we are not arguing the old chicken and egg argument. The experience of most workers with standards, as such, has been that they are not worth the powder to blow them to hell. Regulations do have some authority and there's also a very strong feeling that as regulations approach, you see the biggest effort in many of the plants that we deal with to start doing the engineering and doing the work that's required to bring the production facility within the range of what they perceive might be the regulations.

The danger in your approach as I see it with all respect, Dr. Ham, is that I am not sure we can either educate people fast enough or bring that level of social awareness fast enough, if that's the only approach. I think that the stick you need is probably the regulations that have got some authority. Certainly standards have been almost useless in terms of workers.

Dr. Ham: Mr. Chairman, I am not in disagreement with Mr. Mackenzie. It's a question of balance and when I use the word standard, I guess I mean a regulation. I don't mean just a long list of--

Mr. Mackenzie: Standards or guidelines are what we have usually had and they haven't been worth very much to us.

Mr. Chairman: Thank you very much, Dr. Ham. Questioning has proven that your testimony was very useful. Two o'clock?

The committee recessed at 12:28 p.m.

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November 8, 1982

Dr. J.F. Mustard, Chairman
Advisory Council on Occupational Health
and Occupational Safety
Ministry of Labour
400 University Avenue
Toronto, Ontario
M7A 4T7

Dear Dr. Mustard:

Subject: PACE/OPA Response to the Advisory Council's Request for Comments on the Discussion Paper "The Control of Workplace Carcinogens"

Further to our October 7, 1982 time extension request which you kindly granted, I am pleased to enclose the subject document submitted by the Ontario Petroleum Association (OPA) together with the Petroleum Association for Conservation of the Canadian Environment (PACE).

The OPA represents the members of the Petroleum industry operating throughout Ontario. The members of OPA employ thousands of Ontario residents in the marketing, transportation and refining of petroleum and associated products. As exemplified by our member companies' well developed and long established occupational health and safety programs, we place great importance on the health and safety of our workers. The OPA's member companies are: BP Oil Limited, Canadian Tire Corporation Limited, Gulf Canada Limited, Imperial Oil Limited, M. Loeb Limited, Petro-Canada Enterprises Inc., Petrosar Limited, Shell Canada Limited, Sunoco Inc., Texaco Canada Inc., Ultramar Canada Inc., and United Co-operatives of Ontario.

PACE is a federally chartered organization the purpose of which is to protect the Canadian environment. Currently, eleven oil companies are represented, most of whom operate in Ontario, including BP Canada Inc., Gulf Canada Limited, Imperial Oil Limited, Petro-Canada Enterprises Inc., Shell Canada Limited, Texaco Canada Limited, Ultramar Canada Inc., Petrosar Limited and Suncor Inc.

The OPA and PACE appreciate the opportunity to comment on your Advisory Council's important work and we trust that our comments will be useful in the Council's deliberations.

Yours sincerely,

ONTARIO PETROLEUM ASSOCIATION

G.A. Henderson
President

GAH/mc
Encls.

cc: The Board of Directors

Ontario Petroleum Association and the Petroleum Association for Conservation of the Canadian Environment

October, 1982

INTRODUCTION

The petroleum industry has long placed great importance on protection of the health and safety of its employees. As an advisory resource, the Petroleum Association for Conservation of the Canadian Environment (PACE) has established an Occupational Health Committee which includes physicians, occupational hygienists and a toxicologist.

The Occupational Health Committee of PACE has prepared comments on behalf of the Ontario Petroleum Association (OPA) on: 1) Report of the Special Advisory Committee on Carcinogens, and 2) Discussion Paper: The Control of Workplace Carcinogens.

Section I contains our general comments on the Report and on the Discussion Paper. In Section 2 we comment on the "Issues for Consideration" raised in Section 3 of the Discussion Paper. Some recommendations for further consideration by the Advisory Council are presented in Section 3.

SECTION I GENERAL COMMENTS

A. REPORT OF THE SPECIAL ADVISORY COMMITTEE ON CARCINOGENS

The Special Advisory Committee document is an excellent review of current knowledge of environmentally-induced cancer and environmental carcinogens. The report is well-organized and factual; the "lessons" are commendably professional. It demonstrates that although no occupational cancer epidemic exists in Ontario to warrant extreme urgency, some control of carcinogens, occupational as well as environmental and lifestyle, is desirable.

B. DISCUSSION PAPER — THE CONTROL OF WORKPLACE CARCINOGENS

The Discussion Paper selected one class of carcinogens, occupational carcinogens, and developed one possible control methodology. Our general comments are outlined below:

1. Justification For Regulation
Although a possible regulatory approach is outlined, adequate justification for introduction of regulatory control of workplace carcinogens as a class has not been presented in either the Special Advisory Committee Report or the Discussion Paper. Some of the known human carcinogens are already regulated as Designated Substances in Ontario (e.g. vinyl chloride, asbestos, coke oven emissions). Most, if not all, of the remaining known human car-

cinogens and many of the suspect human carcinogens are either absent or well-controlled in the workplace in Ontario. The major exceptions are sunlight and tobacco smoke. It should be noted that this control has occurred following determination of their potential human hazard and a subsequent consensus that substitution or exposure control is necessary. This control has been achieved without the necessity of specific regulation of carcinogens. We believe that the need for regulation as a means of controlling workplace exposure to carcinogens should be fully evaluated before proceeding with developing regulations.

2. *Resource Allocation*

Any regulation of this magnitude should be accompanied by a Socio-Economic Impact Assessment to ensure that societal resources are assigned to those areas which present the most evident risk to life, health and safety. PACE/OPA believes that those occupational carcinogens which pose a substantial risk are already under control and that available resources should be allocated in proportion to the major causes of death and disability as established by well-founded statistics.

3. *Definitions*

The meaning of many statements could vary substantially dependent on the definition of terms such as chemical, carcinogen, suspect carcinogen, potential carcinogen, exposure, etc. Because current understanding of oncology is in a marked state of flux, it is essential that all terms be carefully defined to avoid possible confusion. The discussion paper lacks clear definitions for the terminology selected.

4. *Total Toxicological Evaluation*

Carcinogenicity, as well as mutagenicity and teratogenicity, should be regarded as only part of an overall schema for total toxicological evaluation of workplace substances. By singling carcinogens out, other potential hazards of equal or greater practical significance may tend to be neglected. We do not believe that carcinogens as a group should be given special regulatory treatment.

5. *Interprovincial/International Uniformity*

Many of the companies represented by PACE/OPA operate nationally. Since member companies comply with each provinces' specific regulations, they are in favour of a reasonably uniform approach on occupational health and safety issues. In the case of workplace carcinogen control, whether regulatory or otherwise, PACE/OPA would support a co-ordinated national approach.

The economic impact on our province compared with other jurisdictions, provincial and international, should be considered when regulations are being developed.

SECTION 2: SPECIFIC COMMENTS ON DISCUSSION PAPER SECTION III "ISSUES FOR CONSIDERATION" (PAGE 20 "THE CONTROL OF WORKPLACE CARCINOGENS)

INTRODUCTION

The "state-of-the-art" in many of the issues raised is very much in the formative stages. Much discussion of each of the issues raised is needed to develop full understanding of the issues and the alternatives. It is premature to consider some of the detailed issues pending resolution of broader policy and strategy issues. The following represents our current "state-of-the-art" views on the issues raised in the Discussion Paper:

ISSUE 1

1. Any initiative aimed towards co-ordination of matters associated with occupational health and safety is welcomed. Such co-ordination, particularly in an international context provides the best arena in which to maximize health benefits while minimizing economic penalties, which may occur when regulations are developed at a local (or national) level. Therefore, we find this suggestion to be highly desirable.

2. We consider that the problem of chemical carcinogenesis should take its place in perspective with many other hazards present within the workplace. The conclusions from the report of the Special Advisory Committee on Carcinogens do not indicate the need to single out carcinogenicity as the highest priority from an occupational health viewpoint. Therefore, we do not agree with this suggestion.

We believe that chemical carcinogenicity is a matter of concern that should be dealt with both in perspective and in a non-emotive manner.

3. As in Issue 1.1. above, any internationalization of priorities is considered to be a desirable objective, and to this end we support the involvement of international agencies and organizations as appropriate.

ISSUE 2

Toxicology is a particularly complicated subject, and it is not always easy to discuss. Chemical carcinogenicity is one of the hardest areas of all in this respect. When considering the optimum means of developing a conclusion on carcinogenicity potential, a scientific advisory committee must be viewed as being the best and most practical. Such a committee must consist of scientific experts in all fields of carcinogenesis, so that any decisions or recommendations are based at the outset on science.

Criteria applied by such a committee must be reviewed periodically.

ISSUE 3

1. We agree that full disclosure of the possible carcinogenicity of a new chemical is appropriate.

2. We consider that limiting reporting requirements for small volume chemicals may be desirable for economic reasons.

ISSUE 4

1. If regulation of chemical carcinogenesis is considered necessary, then we agree that new chemicals should be examined on the basis of their chemical structure. We recognize that it is difficult to draw conclusions from such evaluations.

2. The testing requirements outlined in Pages 12-16 of the Discussion Paper are very sketchy and need elaboration. We do not therefore agree with this suggestion at this time. There are a number of areas of concern with the suggested testing scheme, for example:

a) Technical Aspects:

1. The suggestion that tissue accumulation be considered as a basis for animal tests is somewhat preliminary. Many other factors must also be considered, such as biochemical effects on metabolising systems, potential reactions with genetic macromolecules, etc.

2. The conclusion that 'non-positive' animal tests can still result in a 'suspect carcinogen' categorization is extreme. What testing is necessary to result in a 'non-carcinogenic' category?

3. The two-tier testing system is not justifiable based on the current lack of detailed understanding of the correlation between short term, *in vitro*, tests and potential carcinogenicity. Multiple tiers (at least 3) are needed to extract the maximum amount of data. Possibilities for a 'middle' tier are discussed on pages 167-9 of the Special Advisory Committee Report.

b) Economic Aspects:

The cost of toxicity testing is high, both in financial terms and time. To complete reliable conventional carcinogenicity assays in two species will take at least three years from time of initiation to receiving the final reports. Such a process may not be economically justified for many new materials. This problem provides an additional reason for developing a sequential three-tier testing program. Some of these potential problems should be assessed by a separate advisory committee.

ISSUE 5

We consider it premature to consider such detailed issues at this time. However, since the matter has been raised we offer the following comments:

1. As mentioned on Page 13 of the Discussion Paper, authorities are developing guidelines for the testing of chemicals for potential mutagenicity/carcinogenicity. It is desirable to ensure guidelines are consistent with international authorities.

2a) The National Cancer Insitute (NCI) procedure is now somewhat outdated. It was developed in 1976 and this subject is rapidly evolving. In particular, the NCI did not mention the desirability to determine the chemical kinetics of a substance following absorption by the test animal. This aspect, generally nowadays called 'pharmacokinetics', should be addressed so that meaningful toxicity data can be developed in the cancer bioassay. Current EPA guidelines, as well as Organization for Economic Co-operation and Development recommendations, include pharmacokinetic considerations in the development of a cancer bioassay. We suggest these procedures be mentioned rather than the NCI guidelines.

2b). Some form of battery or tier testing procedure is appropriate, but again consistency with other agencies is desirable.

2c). In theory it is more meaningful to test a commercial sample, but there may be practical difficulties — it is unlikely that a commercial sample will be available early in the development of a new material.

2d). Because of the rapid progress being made in all areas of mutagenicity and carcinogenicity research, any recommendations for testing must be regularly reviewed; probably more regularly than every third year.

ISSUE 6

As indicated earlier, we believe that the need for a system to classify chemicals according to carcinogenic potential has yet to be justified.

There have been many attempts to classify carcinogens over the past few years, and a well-designed three-component system may be acceptable because of ease and simplicity. However, numerous matters of detail will have to be addressed, such as what criteria will be necessary for inclusion in Category II? Will one positive mutagenic assay out of a battery of five be considered sufficient evidence? Will inconclusive animal data result in a Category II classification?

Until such areas are fully discussed, this proposed classification system cannot be properly assessed. It can be stated at this time, however, that provided the classification is carried out by qualified experts, a workable system would result.

ISSUE 7

If regulation is determined to be a necessary way to control workplace carcinogens, then our answers to Issue 7 would be:

1. Regulation may be appropriate for Category I substances.

2. Substitution for Category I substances is favoured, although in this case it would depend on the definition of the word "suitable".

3. If no suitable alternative was available, an occupational control program should be set up on a case-by-case basis, and should include permissible exposure limits.

4. The categories have not yet been scientifically defined, making the area of potential control possibilities ambiguous. Depending on what is meant by "uncertainty" in the given definition of Category II, the matter should be subject to further discussion.

5. Permissible exposure limits for Category II substances could be set but, again, it is difficult as stated in 7-4.

6. & 7. The control of "Designated Substances" under the Occupational Health and Safety Act provides adequate basis for the selection of engineering and work practice controls as well as personal protective equipment.

8. Epidemiological surveillance is desirable for substances impacting on worker health.

9. Occupational health surveillance is also desirable for substances impacting on worker health.

ISSUE 8

1. In theory the determination of potential carcinogenicity of all substances used in Ontario is desirable. However, practically this is a mammoth undertaking.

2. Prioritization for testing is desirable.

3. When the necessity for testing of a specific substance is based on scientific data and there has been a socio-economic evaluation study carried out, responsibility for costs can be addressed.

4. The manufacture or use of an existing substance in a newly constructed workplace should not automatically result in those testing and classification procedures specified for a new substance.

5. Categorization of chemicals currently in use in Ontario could be prioritized systematically but this would be a major undertaking.

ISSUE 9

1. & 2. Substances should be dealt with in a manner appropriate to the degree of hazard associated with them. Regulation may or may not be required.

3. This question is ambiguous and cannot be addressed without appropriate definition.

ISSUE 10

1. Epidemiological surveillance is a useful tool for understanding the origin and course of occupational disease. We question why only populations exposed to established and suspect carcinogens should be identified for surveillance when such a tool could be used to follow populations exposed to other hazardous substances.

We endorse the concept of epidemiological surveillance of working populations at risk, with the reservations that such undertakings are extremely costly and that they are often impractical due to such factors as multiple exposures of many persons in the workforce, and workforce mobility. These reservations must be fully debated if regulation in this area is deemed necessary.

2. Ideally employers should be required to establish group and individual exposure records suitable for epidemiological surveillance. However, such an undertaking suffers problems similar to those outlined in (1), i.e. extremely costly to undertake and impractical to implement for such reasons as sampling method limitations and lack of precise chemical identity. Such factors must be considered in the event that regulation is deemed necessary.

3. Adequate resources should be made available to the Ontario Cancer Treatment and Research Foundation to guarantee continuance of the Ontario Cancer Registry.

ISSUE 11

1. We are of the opinion that members of the workforce should be provided with information on the potential hazards of both old and new chemicals

(not only carcinogens) with which they work on a need-to-know principle. The issue at hand is educating the employee in the safe use of the chemicals handled. If release of potential hazard information to Health and Safety Committees furthers this end, then such information should be provided to them as well. Information pertaining to a substances' hazards including potential carcinogenicity should be appropriate for the intended audience.

2. A mechanism should be developed to ensure that employers provide appropriate information, education and training on the potential health effects of new (and existing) substances.

3. The federal and provincial governments in association with the Canadian Standards Association are developing a system of hazards' labelling in the workplace. Human carcinogens and suspect carcinogens should be treated under this system.

4. If the need for a regulation classifying new substances is determined to be necessary then, provided that manufacturers' trade secret confidentiality is adequately addressed, we agree that an index of such new substances with their category and supporting data base should be made available to the public.

5. The confidentiality provisions of section 34(1)b of the Act should apply in the case of carcinogens, the impact of carcinogens being no worse or better than other toxic materials. Disclosure of information to the workforce and the public should ensure that:

a) manufacturers' confidentiality is adequately addressed;
b) the meaning of testing results and other information provided is explained in laymen's terms;
c) adequate instructions on how to handle carcinogens is provided.

ISSUE 12
We question why carcinogens should be treated differently than other occupational health and safety problems. We believe that non-compliance with workplace health and safety regulations should be dealt with using the penalties set out in the Occupational Health and Safety Act.

ISSUE 13
If regulation is considered to be the only practical means of controlling carcinogens in the workplace, then the issue of research and carcinogenicity should not be addressed separately but should be part of an overall consideration of carcinogenicity.

SECTION 3 — RECOMMENDATIONS

We would like to make the following recommendations:

1. We recommend that the Advisory Council advise the Minister of Labour to appoint an independent consultant to carry-out a socio-economic impact assessment of:

a) The necessity for further workplace carcinogen control in Ontario compared with other workplace risks.

b) A comparison between a regulatory approach (such as provided in the Discussion Paper) and a non-regulatory consensus approach.
c) The effect of unilateral introduction of workplace carcinogen control by Ontario alone.

2. We recommend that, if found to be necessary, workplace carcinogen control methodology be developed by consensus, preferably on a national scale, and taking into account similar actions in U.S., and Europe.

Although a hearing before the Advisory Council has not been requested, PACE is ready to appear on behalf of the OPA at the Advisory Council's convenience in support of this brief.

Conseil de Santé pour le district régional
OTTAWA-CARLETON
Regional District Health Council

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OTTAWA, Ontario K1H 8K7
Telephone (613) 523-6000

13th October 1982.

Dr. J. F. Mustard,
Chairman,
Advisory Council on Occupational
Health and Occupational Safety,
400 University Avenue,
Toronto, Ontario,
M7A 1T7.

Dear Dr. Mustard:

I am writing in response to your letter of June 30, 1982, requesting comments on the Discussion Paper of the Advisory Council on Occupational Health and Occupational Safety.

The request and accompanying documents were referred to Council's Primary Care Board which established a sub-committee for its review. The enclosed final report of the sub-committee has been approved by the Primary Care Board and is supported by this Council.

We recognize the importance of ensuring adequate protection for members of the labour force and thank you for the opportunity of commenting on this important and timely issue.

Yours sincerely,

Wilma Dare

Wilma Dare, M.D.,
Chairman.

WD:mah

Ottawa-Carleton Regional District Health Council

October, 1982

ISSUE 1

National and International Coordination and Cooperation in the Control of Carcinogens.

1. The subcommittee agreed that federal coordination of a nationwide program is essential. Control of importation of chemicals must be a federal responsibility.

2. The federal agency should give a very high priority to the assembling and coordination of available data — data essential to making decisions about the categorization of chemicals.

3. The subcommittee was not familiar with the ILO "Convention concerning prevention and control of Occupational Hazards", and therefore cannot give an opinion in this regard. However it did express the view that the Ontario Ministry of Labour should work in close collaboration with national and international labour organizations.

ISSUE 2 — Advisory Committees

The subcommittee strongly agreed with the formation of an advisory committee to make recommendations with regard to categorization and regulatory controls for chemical substances. The criteria should be subject to periodic review.

The subcommittee did comment that if such advisory committees were to develop in all provinces, efforts must be made to share experience and avoid unnecessary duplication.

Issue 3 — Reporting Requirements for New Chemicals

The subcommittee recommends that there should be full disclosure of information for all new chemicals regardless of the quantity used.

Issue 4 — Testing Requirements for New Chemicals

1. The Minister should establish regulations calling for examination of *all* new chemicals.

2. All new chemicals should be subject to testing.

Issue 5 — Testing Procedures

The subcommittee recommends the development of a standard testing program consisting of:

- a minimum of two short-term tests, carried out on commercial rather than purified preparations and these requirements should be reviewed every three years. If short-term tests are positive, the chemical must be submitted to long term testing in animals.

Issue 6 — Classification of New Chemicals

The subcommittee supports the three categories proposed.

Issue 7 — Control of New Chemicals

1. The subcommittee recommends that *NEW* substances placed in Category I be banned from use regardless of quantity, and use of all such substances should be regulated.

2. If a suitable substitute is available, occupational (or any other) exposure to the substance should not be permitted.

3. If a Category I substance must be used, no detectable exposure in the workplace, to the general population, or to the environment, should be permitted.

4, 5. Category II substances should be treated as suspect carcinogens and a permissible exposure limit should be set.

6, 7. The subcommittee proposes that regulations be such that working with chemicals is safe, so that everyday operations do not require protective equipment.

8, 9. As a general principle, the subcommittee recommends surveillance of all workers regardless of exposures.

Issue 8 — Testing and Classification of Chemicals Not Considered New

1. The subcommittee would like to see the review of currently used substances re carcinogenic potential. There should be a high priority of this review.

2. The subcommittee suggests that the cost be shared by government and industry to ease the financial burden on smaller industries.

3. Currently used chemicals should be subject to regulation if used in a newly constructed workplace.

4. The Ministry should make its review of currently used substances within five years.

Issue 9 — Control of Chemicals not Considered New

1. The subcommittee questions whether use of any Category I chemical in a new plant can be justified. If it does take place, it should certainly be immediately subjected to controls as employed for new substances. If used in an existing plant, it should be subject to immediate controls.

2. Category II substances should be subject to regulations as soon as possible when used in an existing plant (i.e. time to convert equipment, improve ventilation, etc.)

3. Within 5 years all users of chemicals should be required to meet the new regulations.

Issue 10 — Epidemiologic Surveillance

1. The Minister should ensure that epidemiologic surveillance be provided for all workers.

2. Employers should be required to establish appropriate records.

3. The Minister should ensure appropriate resources to the Ontario Cancer Treatment and Research Foundation to continue *and improve* the Ontario Cancer Registry.

Issue 11 — Provision of Information to the Workforce and to the Public

1, 2. The Ministry should ensure that joint health and safety committees, members of labour organizations and the general public be provided with all information on new chemicals including structure. Furthermore consultation services should be provided for labour organizations to interpret this information.

3. The subcommittee agrees with the proposal to develop labelling and colour coding for suspect carcinogens. The subcommittee suggests a symbol as well as colour coding (cf radiation symbol is easily recognized).

4. The public should have access upon request to information regarding new chemicals.

5. Confidentiality of workers who have been found to develop cancer or other health problems should continue to be protected.

Issue 12 — Penalties for Non-Compliance

The subcommittee strongly agrees with the proposal to penalize employers who introduce a known or suspect carcinogen into the workplace or fail to meet standards. The penalty should be large enough to act as a deterrent and be subject to increments as needed.

Issue 13 — Research

The subcommittee would support the exemption of small amounts of Category I chemicals being allowed for experimental purposes. However, regulations for protection of workers should be more stringent than normal.

SUMMARY

1. The Primary Care Board strongly supports the proposed improvements in the regulation of carcinogens in the workplace (except where noted above).

2. The Primary Care Board recommends that tobacco smoke be included as a chemical subject to regulation in the workplace.

3. The Primary Care Board emphasizes that the general population, as well as workers, and the environment as a whole, must be protected from the hazards of known or suspect carcinogens.

Provincial Building & Construction
Trades Council of Ontario
15 GERVAIS DRIVE, SUITE 604, DON MILLS, ONT. M3C 1Y8 (416) 449-4830

November 23rd, 1983.

Ms. Elizabeth Harney,
Executive Assistant to the Chairman,
Advisory Council,
400 University Avenue,
Toronto, Ontario.

Dear Ms. Harney:

Enclosed please find five (5) copies of our Brief on The Control Of Workplace Carcinogens.

Thanking you for your consideration, with best wishes, I remain,

Sincerely yours,

J Duffy

JOSEPH DUFFY
SECRETARY-TREASURER

JD/bh
Encls.
opeiu/343

Provincial Building and Construction Trades Council of Ontario

November, 1982

INTRODUCTION

The Provincial Building and Construction Trades Council of Ontario welcomes the opportunity to comment on the Advisory Council on Occupational Health and Occupational Safety's discussion paper entitled *"The Control of Workplace Carcinogens"*.

Although the workplace case studies on carcinogens in the Special Advisory Committee on Carcinogens Report dealt only with industrial and possibly mining exposures, construction workers across this province are exposed every day to known and suspected carcinogens on their jobs in existing plants, new construction and renovation, repairs and demolition. After all, it was our members of the International Association of Heat and Frost Insulators and Asbestos Workers, AFL-CIO, CFL, whose bodies were counted for the landmark studies carried out by Dr. Irving Selikoff at the New York Mount Sinai School of Medicine.

It is clear that the control and elimination of existing and new carcinogens is absolutely necessary and that a generic cancer policy would overcome many hurdles that presently delay the regulation of such chemicals; however, we appeal to the Council to include control programs for construction workers in the final version. With the exception of the lead standard, where construction workers in existing lead plants are afforded minimal protections, we have been excluded from the Designated Substance Regulations in this province. And although we have been actively involved in advising the Ministry of Labour on their Proposed Regulation Respecting Asbestos on Construction Projects and Related Codes, it is of very real concern to us that in November 1982, there are still no legal requirements to protect construction workers involved in the removal, encapsulation or enclosure of asbestos or in the renovation or demolition of a building containing asbestos. There appear to be no plans to protect us from any other exposures to carcinogens.

THE UNIQUE FEATURES OF CONTRUCTION WORK

There are a number of features of construction work that make the regulation of toxic exposures more difficult, but they also make it even more necessary.

1. Construction workers are a highly mobile workforce, moving right across the province and Canada and in some cases across North America. As well, a construction worker may have six or seven employers in one year. This mobility makes record keeping extremely difficult.

2. The constant change on a construction site makes regular monitoring to enforce exposure limits impossible.

3. Where construction workers are employed in existing plants they are exposed to large numbers of toxic substances and have even less access to information than the plant workers directly involved. The contractor is often unable to fulfill any requirement to inform the workers of the hazards since he is unlikely to know.

4. Demolition of existing buildings and industrial plants can expose construction workers to many cancer causing agents in addition to asbestos. Often they are required to cut up pipes and machinery which still contain unknown chemicals.

5. Where there are multiple contractors on a site, one group of workers may be adequately protected while exposing other construction workers to unknown hazards.

6. Fly-by-night operators, who use school kids or even their own families undercut legitimate contractors who are prepared to protect their workers.

Any generic cancer policy must address these problems in their recommendations for control.

THE PRE-TESTING OF NEW CHEMICALS

We welcome the recommendations for pre-testing of new chemicals, but a mandatory requirement of notification of new chemicals is essential. It must include the chemical formulation, its potential use, its interaction with other chemicals and any test results that are available.

While we essentially agree with the discussion paper's requirements for short-term and animal testing, there are several concerns that we wish to raise:

1. The testing must be carried out by independent, reliable facilities or approved by legitimate international agencies. Unfortunately, there have been too many examples where manufacturers anxious to promote their products have actively suppressed information and labs have produced fraudulent results.

2. Every new chemical must be subjected to long-term animal testing before it is allowed into any workplace. Short-term testing may alert us to potential carcinogens but the fact that there is still a 20% possibility of false negatives, mean that further animal tests are necessary.

3. Even where animal testing shows negative results, we cannot assume that the substance is Non-Carcinogenic, again because of the false negatives inherent in that testing.

THE TESTING OF CHEMICALS PRESENTLY IN USE

We support the discussion paper's recommendation that all chemicals presently in use must be tested and categorized within five years. However, the concerns expressed over new chemical testing apply here as well.

THE CONTROL OF WORKPLACE CARCINOGENS

No new chemical that is found to be a Category I – Carcinogen will be allowed onto any construction site or workplace. Any exemption to this general rule must be approved by a panel with a labour majority, who after all bear the risk of any decision to exempt. At the present time the only exemption that we can forsee is a chemical that is used for medical therapy.

A new chemical that is categorized as a Suspect Carcinogen must be approved for use on an individual basis by that same panel. Where the substance is allowed to be used immediate regulations must apply to construction projects as well. These will involve regulation by procedure, which eliminate construction workers' exposures, full disclosure of the chemical formulation and the carcinogenic hazards, records of exposures to be kept in a central registry, medical monitoring with the physician of choice and the right to refuse without penalty.

A new chemical which demonstrates negative results in animal and short-term testing, should then be tested for other health effects and exposures should be kept to a minimum. These chemicals cannot be assumed to be Non-Carcinogenic, as stated before, and therefore any workers must be followed up to assess the possibility of being wrong.

Where chemicals presently in use are found to be Carcinogens or Suspect Carcinogens, the employer/contractor must make every effort to substitute its use with a "safe" tested alternative. If this is impossible the regulation described above for new chemicals must apply until such time as a "safe" substitute is available.

Negative animal and short-term tests cannot guarantee the safety of existing chemicals either, so that exposures must be kept to a minimum and the exposed workers must be followed-up for epidemiological purposes.

Where there have been epidemiological studies which show negative results and there is good exposure data, large numbers, and at least thirty years of follow-up and preferably over a lifetime, the chemical can be considered to be a Non-Carcinogen if the animal and short-term tests are also negative.

Positive results in any testing must supersede negative results and all chemicals must be assumed to be dangerous until proven that they are not.

THE RIGHT TO KNOW

Construction workers suffer from an even greater lack of knowledge about the exposures on their jobs. Requirements to inform workers of the hazards on the job must be broadened to include the chemical formulation and a full disclosure of all health effects especially carcinogenic effects.

In existing plants, the employer must be obliged to inform all workers in the plant, including construction workers of all potential hazards from any chemicals used, including the chemical formulation, the quantities used, possible interactions with other chemicals, sources of exposure, and monitoring results. This information should be given to the contractor as well, who also has the obligation to inform.

In existing plants, any regulation requiring the reduction of exposure to a no detectable level will apply for construction workers as well. Where construction workers are working with carcinogens, the contractor must inform the plant employer and the plant workers and procedures must be followed that ensure that no "by-stander" is exposed.

Where any contract for renovation, repair or demolition is offered the owner has an obligation to inform any contractor bidding of any cancer causing agent on or in the premises. This information must then be made available to any worker on the project.

Where one contractor is working with a carcinogen on a project, he must inform any other contractors and their workers of the potential hazard and ensure through procedures that no "by-stander" or other construction worker is exposed.

On any project where workers may be exposed to known or suspected carcinogen, the contractor must inform the Construction Health and Safety Branch before work begins. Where the owner is unable to tell the contractor of the presence of any carcinogen a full inspection must be carried out to identify any hazard on that job before work begins.

Any chemical that is classified as a Carcinogen or a Suspect Carcinogen must be properly labelled for any worker to see. Since many of our members may not read English or French the warning labels should communicate without language. A national program of warning shapes for chemicals would be extremely useful.

MEDICAL MONITORING

Any requirement for medical monitoring that is included in a regulation controlling workplace carcinogens must ensure the worker's right to go to the physician of his or her own choice. The Krever Commission's Report on Confidentiality of Health Records merely confirmed our suspicions that employers abuse such information. As well, the high mobility of our workforce means that employer based health services make no sense. Any medical monitoring required under a regulation must be paid for by the employer or contractor. Where there are multiple employers or contractors the cost could be shared through a fund based on assessments similar to the WCB.

EXPOSURE RECORDS

Since monitoring of exposure on construction sites makes no sense, there will be no exposure records to forward to the physician. However, the fact of the exposure must be registered by the contractor and kept in a central registry, perhaps with the Ministry, for future compensation or research purposes.

PENALTIES

We consider the violation of any regulation that places workers' lives at risk to be a very serious offence and should carry a substantial penalty. However, a contractor's failure to inform workers of the introduction of a carcinogen is surely not more serious than a contractor's failure to ensure that the support systems on trench walls comply or that scaffolds are capable of supporting the required load. Risking workers' lives in any way is totally unacceptable.

CONCLUSION

Construction workers deserve full protection against cancer causing agents on their jobs as well. Because of the mobility of our workforce, we would welcome a national program of testing, classification and control; however, Ontario must not use the failure of the federal government to move in this direction as an excuse not to protect the workers within this jurisdiction.

A concerted effort must be made to remove all known carcinogens from our workplaces through the substitution of "safe" alternatives. But even when chemicals are removed from industrial plants, they are often left in the buildings that we must renovate or demolish. The experience with asbestos has shown that even if its use was completely eliminated construction workers will continue to be exposed well into the future.

There is no "safe" level of exposure to any carcinogen! Any regulation controlling the use of a known or suspected carcinogen must ensure that the exposure is eliminated through procedural controls. Our endorsation of regulation by procedure on construction projects must not be misinterpreted as an acceptance of exposure.

And finally, we reject the entire concept of "acceptable risk". Not only can no one assure us that risk estimations from animal or even human studies have any validity but the entire process of trading off workers lives in a cost-benefit equation is morally reprehensible. The object of the entire exercise must be to prevent cancer!

PUBLIC SERVICE ALLIANCE OF CANADA

233 GILMOUR
OTTAWA, ONT. K2P 0P1

ALLIANCE DE LA FONCTION PUBLIQUE DU CANADA

December 3, 1982.

Dr. J.F. Mustard, M.D.,
Chairman,
Advisory Council on Occupational
Health and Occupational Safety,
15th Floor, 400 University Ave.,
Toronto, Ontario.
M7A 1T7

Dear Dr. Mustard:

Enclosed is a submission from the Public Service Alliance of Canada regarding the Advisory Council's Discussion Paper - The Control of Workplace Carcinogens. While parts of our submission relate to specific concerns we have arising out of our own experiences, the bulk of our document has reference to the Ontario Federation of Labour's submission to the Advisory Council. We fully endorse their submission. In particular, we applaud their detailed prescriptions for minimizing and eventually eliminating the presence of carcinogens in our workplaces.

The Council and the Ministry of Labour are to be congratulated for this undertaking. The revised policy will be too late for many workers but we sense a determination on all sides that it will not be too little.

Please keep us informed of all further activities of the Council as they relate to the control of carcinogens in the workplace.

Yours sincerely,

Daryl T. Bean

Daryl T. Bean,
Executive Vice-President.

DTB:mrb
Encls.

The Public Service Alliance of Canada

December, 1982

The Public Service Alliance of Canada is a union representing some 175,000 members, the overwhelming proportion of whom work for the federal government. Why, then, do we wish to go on the record before a provincial body grappling with the control of workplace carcinogens? The reasons are not mysterious:

1. We do have some members who fall within the scope of the Health and Safety Law of Ontario.

2. Almost one-half of our membership work in Ontario. Any policy innovations concerning carcinogens in provincial workplaces will ultimately benefit those members.

3. In the event of injury or death on the job, our 85,000 members in Ontario have very direct links with the Province through the Workers Compensation Board.

4. If the Ministry of Labour is sufficiently foresightful and courageous, millions of working people will benefit. The entire labour movement can rejoice over that.

Let there be no mystery either about the hazards faced by our members working in Ontario. In labs, smelters and tar sands, in offices, institutions and vehicles, manipulating typewriters and high-tension wires, using polarographs and photocopiers, they confront the modern workplace. Many of them work at video display terminals, and in this regard, we would like to echo the Ontario Federation of Labour's statement that the need exists "to expand testing requirements to any possible cause of cancer in the workplace."[1] The question marks about VDTs stem from uncertainty as to the health effects of long-term exposure to low levels of radiation. A copy of our position paper on this matter is enclosed for the Council's consideration.

In other forums, the Alliance has referred to the rhetoric about rights which accompanied the proclamation of our new constitution. We put forward the view that labour needs a charter of rights on health and safety and that such a charter would assert:

- the right to know;
- the right to participate;
- the right to protection;
- the right to refuse.

It may be expeditious to organize our remarks on the Advisory Council's Discussion Paper and the OFL submission around those four rights.

I. THE RIGHT TO KNOW

The OFL document is quite eloquent on this subject. We share their strong feelings. The institutionalized ignorance of our workplaces must be overcome if workers are to have more control over the hazards they confront at work. In this regard, we heartily endorse the OFL's five-point response to *Issue #11 — The Provision of Information to the Workforce and to the Public*. A clear legal duty is needed to ensure that employers inform workers about the contents, possible effects of and precautions to be used for all chemical substances in the workplace, especially carcinogens. Reliable, relevant, comprehensive, and comprehensible information is a fundamental need for workers.

2. THE RIGHT TO PARTICIPATE

Participation in this context refers primarily to *Issue #2 — Advisory Committee(s)*. We support the OFL view that a permanent committee should be established with full-time paid representatives of organized labour and management. The majority on the committee should represent workers because "it is crucial that we begin to see occupational health and safety from the point of view of the worker."[2] More fundamentally, as the OFL indicates, "they are the ones who must assume any risks from the decisions involved."[3]

3. THE RIGHT TO REFUSE

On matters of health and safety, most particularly those involving carcinogens, the Alliance firmly believes there is nothing negative about saying no! Indeed the right to refuse work considered dangerous to oneself, a fellow worker or the public may be the single most positive way for workers to protect their health and safety. It asserts the primacy of the worker as the one who knows and the one who experiences the dangers of the workplace. The OFL submission makes specific reference to this right in dealing with *Issue #7 — The Control of New Chemicals*. In both instances cited – exemptions from Category I and specific decisions on Category II – the ability to exercise this right without penalty is critical. Workers must not be subjected "to the horns of a dilemma which forces them to risk either their jobs or their health."[4]

4. THE RIGHT TO PROTECTION

We come to the heart of the matter. Our feelings are particularly acute on this because, as Council members may know, the majority of federal public service employees have no legislation protecting their lives and limbs. All they have is a policy developed by the Treasury Board and allegedly policed by them; however, responsibility for administering the policy is diffused among fifteen different departments and agencies, all of which have varying degrees of involvement in implementation and enforcement.

No such confusion seems to attend the schema proposed by Council and modified in the OFL's submission. The tenet that "all chemcials or physical agents must be considered guilty until proven innocent"[5] is a fundamentally necessary perspective. The modified classification system in the OFL's document is superior to that of the Council's proposal in that it codifies our fears about potential carcinogenicity. There is a basis for these fears in that conclusive identification of carcinogens is a complex matter, on the frontiers of science. Hence, the OFL's Category III doesn't strike us as an excess of caution and is therefore commended to the Council.

We have already made reference to *Issue #7 — The Control of New Chemicals* but we would like to return to it to underline one other aspect, namely this statement: "In general, Category I new chemicals will not be allowed into any workplace. But where Category I or II are allowed, the no detectable levels will be met through engineering and workplace controls only."[6] Such controls will necessitate enclosure and isolation, for only in this way can we achieve zero risk which is, in our view, the only acceptable risk.

In conclusion, the Alliance recognizes that courage and honesty will be required to adopt strong regulations regarding the identification, classification, and control of carcinogens and suspect carcinogens. Concepts such as "zero exposure" and "irreducible minima" are not just questions of technology but of economics and politics. Enormous pressures will be brought to bear upon the Ministry to temper their proposed classification system, to be less than zealous in whatever schema is adopted for the protection of workers. These pressures must be resisted. The spectre of death and disability must be eliminated from our workplaces.

REFERENCES

1. Submission by the Ontario Federation of Labour, p. 319.
2. Reasons, Ross, Paterson, *Assault on the Worker*, P. XIV.
3. O.F.L. *Op. Cit.*, p. 320.
4. Nicholas Ashford, *Crisis in the Workplace*, p. 192.
5. O.F.L. *Op. Cit.*, p. 320.
6. *Ibid*, p. 327.

Shell Canada Limited
Head Office
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Telephone (416) 597-7111

October 13, 1982

Dr. J.F. Mustard
Advisory Council on Occupational
Health and Occupational Safety
400 University Avenue
TORONTO, Ontario
M7A 1T7

Dear Sir:

SUBJECT: CONTROL OF WORKPLACE CARCINOGENS

We refer to your letter of June 30th on this subject and apologize for the delay in replying.

Our Medical, Industrial Hygiene, Toxicology and business personnel have jointly reviewed the documents provided and specific comments are appended. They are summarized as follows:

1. The Report of the Special Advisory Committee is generally excellent, and can form a basis for constructive and realistic control measures. Unfortunately, the Discussion Paper does not take advantage of that fact.

2. The Discussion Paper concentrates on proposed regulations for potential carcinogens, whereas the Report shows that occupational carcinogenicity should not be considered in isolation. It would seem far more reasonable to use the existing Ontario OHS Act as the basis for any additional control considered necessary. For instance, guidelines for toxicity testing of new chemicals could be drawn up, and could include studies which address mutagenic/carcinogenic potential.

3. We find the proposals relating to the testing of existing chemicals to be extreme and unworkable from a technical viewpoint. For example, the resources are not available for the suggested evaluation of carcinogenic potential of all existing substances within a 5 year period. In addition severe economic difficulties would result for Ontario's manufacturing industry in the form of costs for major studies and delays in developing new facilities. The issue of evaluating the carcinogenic potential of existing substances must be coordinated on at least a national and preferably an international level.

.../2

We hope the above comments and the detailed notes appended will be of use to you. We would be very pleased to answer any questions you might have and to participate in further discussions on this subject.

Yours truly

G.C. Granville
Corporate Toxicologist
for:

Corporate Toxicologist
Corporate Medical Director
Manager, Industrial Hygiene & Product Safety
Business Manager, Industrial Chemicals

Shell Canada Limited

October, 1982

A. COMMENTS ON REPORT OF THE SPECIAL ADVISORY COMMITTEE ON CARCINOGENS

The general tone and message of this report is impressive — it is one of the best reviews of occupational cancer we have read. Our comments on it are mainly minor, but for completeness, they should be mentioned:

a) Overview:

A summary would have been helpful. The lay public are aware that carcinogens produced and emitted by industry can affect man and believe that a large proportion of human cancers are a result of 'industrial chemicals'. The 'Lesson' on page 161 should be placed in a more prominent position.

b) Specific Comments:

Page 160, last paragraph: Comments about a possible future increase in cancer incidence due to the 'recent' introduction of chemicals have been made for more than 10 years, and no such increases are now seen. Still, one cannot argue with the statement — it just seems to be an unlikely possibility.

Page 161, second paragraph: We do not agree that "several hundred new compounds each year" are introduced into Ontario workplaces. This comment should be challenged because it forms the basis of the argument that there is a huge potential problem with untested, new chemicals whereas the truth is very different. In fact, very few new compounds are introduced each year.

Page 162, Lesson. Another excellent comment.

Page 163, final paragraph: The NCI guidelines are now somewhat outmoded. We have two comments on this aspect:

1. These NCI guidelines, which date from 1976, recommend the use of "maximum tolerated doses" (MTD) to be given to test animals. Such heroic levels often overwhelm the biochemical integrity of a living organism and give rise to questionable results. A cautionary statement with respect to highest dose tested would seem appropriate.

2. A number of agencies have recently prepared guidelines for cancer testing in animals, such as the USA-EPA, the WHO (via the IARC) and the OECD. We suggest such guidelines be mentioned in the report.

Canadian toxicologists played a major role in preparing the OECD guidelines.

Page 164, first paragraph: The cost of cancer studies is generally more like $1,000,000.

Pages 164-169: The discussion on short-term tests is incomplete but nevertheless is a good review insofar as it goes. Not mentioned, however, are the known limitations of mutagenic studies. It is still not certain that damage to DNA is the critical event in the production of cancer, and therefore a number of the suggested tests are still in an experimental phase. Nevertheless, we agree that such tests should form a major part of the evaluation of potential carcinogenicity of a chemical, and that their further development and use should be further encouraged.

Page 170, Second paragraph: A good Summary.

Page 170, Third paragraph: Due to the complicated relationship between mutagenicity and carcinogenicity it is insufficient to use a single 'battery' or 'tier' of mutagenicity tests as being the basis for an assessment of carcinogenicity. Further tiers are needed: current opinion is that a second tier, consisting of *in vivo* mutagenicity evaluations (including those discussed in pages 167-169 of the document) needs to be built into any proposed testing programme.

Page 171, First paragraph: The recommendation should be changed to OECD guidelines (see our earlier comment).

Page 171, Second paragraph: We cannot agree more strongly with this concept and recommendation. Without such an expert advisory committee the complicated problems associated with the generation of toxicity data and its extrapolation to man will not be dealt with effectively, leading to scientific, political and economic problems.

Pages 171-178: We believe the inclusion of epidemiological matters to be a very positive aspect of the Report and consider the recommendations for an on-going surveillance system to be fundamental to any control programme dealing with toxic chemicals.

c) *Summary on the Above:*
A good document, which, with only a few modifications, form excellent background for a realistic and effective policy on carcinogens, should one be considered necessary.

B. COMMENTS ON THE DISCUSSION PAPER OF THE ADVISORY COUNCIL ON OCCUPATIONAL HEALTH AND SAFETY

a) *Overview:*
Unlike the Report, the Discussion Paper does not appear to be a well-researched document and fails to consider the necessity, practicability and costs of the recommendations made.

b) Specific Comments:

Chapter I

- The introduction does not develop a strong case for the necessity of introducing regulations on carcinogens in isolation from existing OHS legislation.

- *Page 1;* Second half, second paragraph: The messages are confusing: the relevance of internal cancers being incurable has nothing to do with the following statements about uncertainty of mechanisms and dose-response relationships. The same logic can be used to ban motor cars, wood-burning or cooking.

- *Page 5-6:* Principle of ALARA. The concept of ALARA is well known, and the only difficulty is in the definition of 'reasonable'. This area is a complicated mixture of science, technology and economics and requires prolonged and frequent debate to ensure that practicality is maintained.

- *Page 6;* First paragraph: This paragraph confuses us as it appears to be full of 'double-talk'. Our concern here is the same we have throughout the Introduction — that the Discussion Paper makes no attempt to put the matter of occupational carcinogenesis into any realistic context. The paper could emphasize that occupational cancer is of concern, but that it is not to be taken out of context of the entire subject of occupational health and therefore needs to be discussed objectively. The Report of the Advisory Committee does allow the Discussion Paper to develop this argument; unfortunately, it does not happen.

Chapter III
Pages 9-11: We agree with the comments here, particularly the recommendation to set up an advisory committee. Our only concern is the comment in the middle of page 10, that the committee should be "broadly representative of the various groups". If the committee is not completely technical in content, it will not perform a proper function. A phrase mentioning "qualified experts within the area of occupational health" should be included somewhere. The final sentence on page 11 is not compatible with the other functions of the committee: it refers to a strictly political matter and therefore needs to be coordinated by the Ministry.

Pages 12-15: The proposal on these pages is fundamental to the whole discussion document. A generic characterization of chemicals into one of three classes will doubtless meet with strong opposition. We are in favour of it *PROVIDED* the placement of a material into one of the categories is carried out by a scientific advisory group. Otherwise, we would not be in favour. Our reasons for stressing the 'science' aspect is that toxicology data do not neatly place chemicals into 'positive' or 'non-positive' categories. These will always be a 'grey' area where one cannot be sure; we are concerned that a majority of chemicals may end up as being 'suspect' because of non-technical considerations. In our opinion, Category II chemicals will be those which fall within the 'grey' area and should not consist of a very large number of materials. As long as science is the basis by which a material is categorized, then we cannot foresee the proposed system being inadequate. We find the comment made in the middle para. of page 14 to be somewhat extreme in this respect: a scientific advisory committee will generally be able to sort this problem out.

There are a number of problems in the proposals that will require careful discussion. In particular, the last para. on page 12 calls for full disclosure of data before manufacture commences. Such a proposal is not acceptable from a business point of view (one is not likely to invest in building a manufacturing facility only to see it stand idle, whilst hoping for "good" results from a toxicity test which can easily take up to 3 years to complete), but is also impractical from the technical point of view.

Pages 16-18: This section is somewhat "loose" in concept. Without seeing specific proposals, it is hard to criticize, but we do not like the tone of the section. In particular, the proposal (8th line, page 17) that no carcinogen be used unless duly authorized will be unenforceable under certain circumstances, e.g. benzene in gasoline, aflatoxin in peanut oil processing. The middle para. of page 17 also seems potentially impractical. More definition of the proposals will be needed before commencing further.

Pages 18-19: We find this section proposes extreme actions and we have some major concerns. Our specific comments are as follows:

1. The task of categorizing existing substances and determining whether they had been adequately tested for carcinogenicity will be a major one. We doubt that sufficient experts will be found to review relevant lists and also question how these lists will be drawn up. Besides this, we have serious reservations as to the relevance and need for such an action — there are other, easier ways of controlling carcinogens such as via existing OH & S legislation.

2. The suggestion that manufacturers should pay for all testing will place the Ontario manufacturing industry at a major disadvantage on a national and international level.

3. *(Top Page 19):* The suggestion that cancer studies should be initiated for materials used in a new plant would probably effectively prohibit any plans to invest in such a plant. A degree of pragmatism is needed, including an understanding of potential exposure levels. plant operations, etc.

4. We have no specific criticisms on the rest of page 19, but suspect the proposals are not readily workable.

C. COMMENTS ON IDENTIFIED ISSUES (CHAPTER III OF DISCUSSION PAPER)

Issue #1:
Part 1. Yes, a national consensus is very desirable.
Part 2. No, this would involve an excessive waste of resources.
Part 3. Yes, involvement of international agencies is a constructive step towards international coordination of health and safety matters.

Issue #2:
Yes, but this committee must be composed of qualified experts.

Issue #3:
A guarded yes, although matters of confidentiality must be addressed.

Issue #4:
Part 1. We doubt the relevant expertise is available, but consider a theoretical evalution to be a worthwhile first stage in an assay for potential carcinogenicity.
Part 2. Yes

Issue #5:
Part 1. Yes.
Part 2.
a) No, use the OECD proposals and mention the need for pharmacokinetic studies.
b) At least two. A battery of tests is even better.
c) It may be difficult to obtain commercial samples of a new material. This aspect of testing should be left to experts within the manufacturing company.
d) Yes, if not more frequently.

Issue #6:
We are concerned that under the classification system discussed, most chemicals will end up in Category II. This may not happen if the advisory committee must be scientifically competent.

Issue #7:
1. Yes.
2. Depends upon the situation. There may be powerful technical/commercial/financial/hygiene aspects which need to take precedent over substitution.
3. This needs to be evaluated on a case-by-case basis.
4. No, they should be treated as unknown.
5. Yes, because there is no realistic alternative.
6. We cannot see another workable system.
7. Yes, in general.
8. Yes, in general.
9. Yes.

Issue #8:
1. No, it is not practical nor necessary.
2. We think this will be very difficult.
3. The economic cost and resulting socio-economic impact will be enormous, and will really be met by the consumer.
4. No, for reasons given earlier.
5. It could be tried with respect to an Ontario list, but it will be very difficult to do well.

Issue #9:
1.a) Yes, from a toxicology view, but this may well result in preventing new facilities from being constructed.
1.b) Depends upon many factors, but in general, yes.

2.a) Yes, as for 9(1)(a), but also depends upon definition of "appropriate".
2.b) Why? It perhaps should be as for 9(1)(b).
3. The business implications may be important here; incentives may prove helpful.

Issue #10:
Yes to all parts, although definition of "suspect" carcinogen is far too broad in this context.

2. We would have thought that this aspect was covered under existing OH&S regulations. Confidentiality aspects may be important.
3. Yes; but this is now on-going.
4. Apart from confidential aspects, it seems acceptable but not really necessary.
5. Full disclosure will be preferable in the long-term.

Issue #12:
No.

Issue #13:
No.

CORPORATE TOXICOLOGIST
CORPORATE MEDICAL DIRECTOR
MANAGER, INDUSTRIAL HYGIENE & PRODUCT SAFETY
BUSINESS MANAGER, INDUSTRIAL CHEMICALS

stelco

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November 10, 1982

Dr. J. F. Mustard
Chairman
Advisory Council on Occupational Health and
Occupational Safety
400 University Avenue
Toronto, Ontario, M7A 1T7

Dear Dr. Mustard:

THE CONTROL OF WORKPLACE CARCINOGENS

Stelco Inc. would like to thank the Advisory Council for the opportunity to comment on issues raised in the document entitled "The Control of Workplace Carcinogens."

Since steel, not chemicals, is our main product, our comments will be brief.

We would be pleased to discuss these comments and recommendations with you if required.

Yours very truly
Stelco Inc.

H. H. Eisler
Manager, Environmental Control

HHE*k
Attach.

Stelco Inc.

November, 1982

A — GENERAL

1. Regulation and Control

We do *not* agree that a different regulatory approach is required for carcinogens. In our opinion, the testing and control of carcinogens can be accomplished within the existing framework of legislation and regulations. Nor would we favour the establishment of a separate advisory committee to advise on the classification and control of specific carcinogens. Program development for carcinogens should be done by the appropriate branches of the Ministry of Labour.

We support a substance by substance approach with full opportunity for comment on each substance by affected parties. (Ref. Issue #2)

2. Substitute Materials

Where substitute materials are proposed, full consideration must be given to technical feasibility and the expected benefits compared to the economic impact. (Ref. Issue #7)

3. Exposure Limits

Many carcinogens and suspect carcinogens are essential industrial materials and zero detectable exposure is often not achievable. Exposure limits will therefore have to be established as has already been done in Ontario for asbestos, vinyl chloride and coke oven emissions. (Ref. Issue #7)

4. Testing of Chemicals

An extravagant duplication of effort will result if onus is placed on the *user* to test new or existing chemicals. This testing should be done at the manufacturing level. (Ref. Issue #8)

5. New Plants

Obviously, the construction of a new plant represents an opportunity to engineer out problems related to chemical exposure and much effort is being expended to do this. However, the idea that new plants would be required to test all chemicals at the *user* level would be wasteful duplication and a major barrier to job creation in Ontario. This requirement should be deleted in favour of a phased program to evaluate all suspect carcinogens over a reasonable period. This period will need to be longer than 5 years. (Ref. Issues #8 and 9)

6. Classification

The three Categories for carcinogens proposed in the document are insufficient. Alternative categories are proposed for consideration. (Ref. Issue #6)

1. Human carcinogens
a) Potent human carcinogens to which no exposure would be permitted.
b) Human carcinogens for which exposure limits have been established.
c) Human carcinogens for which exposure limits have yet to be established.

2. Suspect Carcinogens
a) Suspect human carcinogens.
b) Substances which have shown some evidence of carcinogenicity.

3. Not Determined
Substances which have not been assessed or where sufficient data is not yet available to conclusively classify the substance as non-carcinogenic. This category is essential to avoid branding everything as "Suspect."

7. Uniformity Across Canada
In order to facilitate interprovincial trade, which is particularly important to this Province, Ontario should promote a Federal program to establish uniformity across Canada in this field.

B — SPECIFIC COMMENTS

Issue #1
We agree that the efforts of federal and provincial governments and of various ministries within each jurisdiction should be coordinated in order to achieve efficiency, a uniform approach, and not hinder product trade unduly. The first priority should be the assembly of available data.

Issue #3
Information from manufacturers or suppliers on the carcinogenicity (and other toxic and hazardous properties) of most commercial products is presently available to employers and the Ministry on request. This information is often given in confidence. Information on the hazards should be made available to those concerned but confidentiality of individual constituents should be respected when requested by the manufacturer.

Issues #4 and #5
We agree that adequate assessment of new chemicals is required. Much of this work is already being performed.

Since, in general, we are not in the business of producing new chemicals we will not comment further.

Issue #8
The job of assessing or classifying chemicals presently in use should be approached in a coordinated and orderly fashion giving priority to chemicals used in Ontario. No time frame or deadline should be set without due regard to the size of the job and the resources available.

PENALTIES

The Occupational Health & Safety Act provides an adequate system of penalties for contravention of the Act or regulations. There appears to be little logic to support increased penalties in relation to this hazard as opposed to others.

Therefore, penalties should continue to be those established by the Occupational Health & Safety Act.

URW

United Rubber, Cork, Linoleum &
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Milan O. Stone, *President*
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October 14, 1982

J. F. Mustard, M.D., Chairman
Ontario Advisory Council on
Occupational Health and Safety
400 University Avenue
Toronto, Ontario, Canada M7A 1T7

Dear Doctor Mustard:

The United Rubber, Cork, Linoleum and Plastic Workers of America, AFL-CIO, CLC has long been concerned and active in any effort to improve the working environment not only of its membership, but also of workers everywhere.

Our International Union, although small (150,000 members), in comparison to Steelworkers, Teamsters, and Autoworkers, has been in the forefront and has spearheaded activity through collective bargaining, legislative interaction, and specific petitions to the U.S. Department of Labor -- not only regarding carcinogens, mutagens, teratogens, and other harmful and toxic chemicals, but also for enforceable federal legislative standards in areas of occupational safety. The URW sets worker health and safety as priority issues in its representation and service to its members both in the U.S. and Canada.

For ten years, through negotiations, the URW has supported extensive epidemiological studies which scientifically documented and verified that Rubber Workers were at exceedingly high risk to numerous forms of occupationally induced cancer and other chemically caused diseases. Just this year, we negotiated another historic labor-management agreement for early cancer detection and multiphasic screening for about 40,000 of our members in the U.S.

Needless to say, our union has dedicated its resources and negotiated funding to preserve and save the lives of our members and their families from the ravages of cancer. The observed mortality and morbidity among our members has taken its toll in lives, suffering, and economic impact on the worker, his family, and his employer from the standpoint of medical cost and lost production.

Volume 28 of the IARC Monographs on the "Evaluation of Carcinogenic Risk of Chemicals to Humans: The Rubber Industry" (April, 1982) itemizes non and suspect human carcinogens and documented animal carcinogens used in the manufacture of rubber products. The list is too extensive to include in this communication. Exposure to carcinogenic or leukemogenic agents such as benzene, vinyl chloride monomer, acrylonitrile, and asbestos which, although regulated by the U.S.'s OSHA, are currently being considered for strictor regulations. New data concerns the need for such action.

United for Freedom

Our membership in the U.S. and Canada involved in plastics manufacture, are facing exposure to phthalates which are documented producers of cancer in experimental animals, e.g., Di-ethylhexyl phthalate (DEHP), Butylbenzylphthalate (BBP), and Di-ethylhexyl adipate (DEHA).

Even more serious is the overwhelming events that workers in the rubber industry are exposed to significant levels of nitrosamines generated in processing operations. The U.S. has been conservative in regulating or even recognizing potent carcinogens. Canada, Ontario Province included, has acted slowly and regulations which do exist regarding workplace carcinogens, is generally too conservative or non-existent. The URW feels that responsible federal occupational health specialists in both countries are not supported by their legislators. Industry objects to any regulation, refuses to accept scientific documentation, and pleads economic hardship due to regulatory compliance and threatens workers with plant closures and job loss. Indiscriminate and capricious employers feel that the dead body count is not high enough to merit their concern.

The time to enact realistic, preventive, and protective enforceable regulations (Provincial or Federal) is now, before the documented dead bodies are piled too high.

Your discussion paper, "The Control of Workplace Carcinogens," which is generally well-written, will be briefly critiqued by the following topic comments:

BRIEF CRITIQUE:

1. (page 5) The ICRP notion of acceptable risk is practically, socially, morally, philosophically, and ethically unacceptable -- there is no acceptable risk, especially if one deals with carcinogens.
2. (page 6) We agree that "no benefit to society can be worth subjecting the workforce to a risk which we are not able to quantify at this stage."
3. (page 6) It is impossible to quantify (analytically) zero exposure.
4. (page 7) When dealing with human susceptability, no one can set a "SAFE LEVEL" with surety.
5. (page 7) In the rubber industry the generation of non carcinogenic bi-products classified as nitrosamines must be considered in Ontario's or Federal cancer regulatory processes.

Rather than get into an extensive dissertation regarding "issues for consideration" the URW would prefer to respond to the thirteen issues when an oral presentation date or time has been set.

The URW's International President, Mr. Milan Stone, its Director of Industrial Hygiene, Mr. Louis S. Beliczky, and the URW's Canadian Director, Mr. William Punnett, request a total of approximately 40-60 minutes for a presentation. If you in some way could notify our office regarding this matter, we would be most appreciative. It is important that the Ministry understand the strong feeling labor has about the indiscriminate and uncontrolled use and recognition of carcinogens in the workplace.

It is very possible that the ICEF (International Federation of Chemical, Energy and General Workers' Unions) would also be represented in any testimony procedure regarding regulatory activities initiated to protect workers from the ravages of environmental carcinogens.

With best regards and success to your endeavors, I remain

Yours very truly,

Louis S. Beliczky,
Director of Industrial Hygiene
URW International Union

LSB:pjf
opeiu 339
C: International Officers
District Director Punnett
Occupational H & S Specialist Krueger
Charles Levinson, Secretary General (ICEF)
Hector Acuna, Director, Pan American Health Organization
Peter Infante, M.D., OSHA
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